EXHIBIT BB

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM, PRODUCTS LIABILITY LITIGATION — MDL No. 2327

This Document Relates to:

Carolyn Lewis, Et Al v. Ethicon, Inc.
Case No. 2:12-CV-04301

IN THE DISTRICT COURT, 95th JUDICIAL DISTRICT
DALLAS COUNTY, TEXAS

Linda Batiste,
Plaintiff,
v. — Cause No. DC-12-14350
John Robert McNabb, M.D.,
Johnson & Johnson and Ethicon, Inc.,
Defendants.

DEPOSITION OF HOWARD C. JORDI, Ph.D.

Wednesday, October 30th, 2013

9:05 a.m.

Held At:

Jordi Lab
200 Gilbert Street
Mansfield, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RPR, CLR, CSR #149108

APPEARANCES:
FOR THE PLAINTIFFS:
BY: BENJAMIN H. ANDERSON, ESQ.
ANDERSON LAW OFFICES, LLC
1360 West 9th Street, Suite 215
Cleveland, Ohio 44113
216-589-0256
ben@andersonlawoffices.com
-and-
BY: DANIEL J. THORNBURGH, ESQ.
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ PLLC
17 East Main Street, Suite 200
Pensacola, Florida 32502
850-202-1010
dthornburgh@awkolaw.com

FOR THE DEFENDANTS ETHICON, INC., and JOHNSON & JOHNSON:
BY: DAVID B. THOMAS, ESQ.
THOMAS COMBS & SPANN, PLLC
300 Summers Street, Suite 1380
Charleston, West Virginia 25301
304-414-1807
dthomas@tcspllc.com

APPEARANCES VIA SPEAKERPHONE
FOR THE PLAINTIFF CAROLYN LEWIS:
BY: CALLE M. MENDENHALL, ESQ.
FREESE & GOSS PLLC
Regions Harbert Plaza 1901
6th Avenue North
Birmingham, Alabama 35203
205-871-4144
calle@freeseandgoss.com

FOR DEFENDANT DR. JOHN McNABB in the Batiste case:
BY: PHILIPA M. REMINGTON, ESQ. (AM)
CHARLES A. ESTEE, ESQ. (PM)
THIEBAUD, REMINGTON, THORNTON, BAILEY, LLP
1445 Ross Avenue, Suite 4800
Dallas, Texas 75202
214-954-2210
premington@trtblaw.com

INDEX

EXHIBITS

P R O C E E D I N G S

HOWARD C. JORDI, Ph.D.,
having been first duly identified and sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. THOMAS:

Q. Good morning, Dr. Jordi.
A. Good morning.
Q. I introduced myself to you before the deposition. My name is David Thomas, and I represent the Defendants in the case. And I'm going to take your deposition in two matters, the Carolyn Lewis matter and the Batiste case from Texas.
You understand that?
A. I do.
Q. We're here in your offices in Massachusetts?
A. Yes, we are.
Q. And is Massachusetts your home?
A. It is.
Q. Okay. Would you state your full name for the record, please?
A. Howard Craig Jordi.

Page 6

Q. And you're a Dr. Jordi, correct?
A. That's correct.
Q. A Ph.D doctor?
A. A Ph.D doctor.
Q. Not a medical doctor?
A. Not a medical doctor.
Q. And in what area is your Ph.D?
A. Biochemistry.
Q. What is a biochemist?
A. A biochemist is one who studies the reactions of chemicals in the body.
Q. Okay. Dr. Jordi, I've been provided two reports in this case. I'm going to mark as deposition Exhibit Number 1 what's been provided to me as your Rule 26 expert report of Howard Jordi, Ph.D in the Carolyn Lewis case.
A. Okay.
(Whereupon, Jordi Exhibit Number 1, Rule 26 Expert Report of Howard Jordi, PhD in the Carolyn Lewis case, was marked for identification.)
MR. THOMAS: And I'm going to mark as Exhibit Number 2 what's been provided to me as a document titled Final Report for Linda Batiste.

Page 7

(Whereupon, Jordi Exhibit Number 2, Document titled Final Report, Linda Batiste, was marked for identification.)
BY MR. THOMAS:
Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to --
A. I was going to say it didn't seem thick enough.
Q. It's half as thick as you expected it to be.
A. Yes.
Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case.
Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case?
(Witness reviewing documents.)
MR. ANDERSON: I'd just like for the record to reflect that it's an almost 800 page report, and he's trying to leaf through it as best he can and to try to determine if it's

Page 8

final, rather than looking at each and every page, he's trying to do the best he can in the interest of time.
MR. THOMAS: It's 847 pages, and I'll represent to you that we copied it as best we could and produced it for him, and I'm just trying to get him to identify it as best he can.
MR. ANDERSON: So stipulated.
MR. THOMAS: The Batiste report is some 240 pages, and I don't expect him to go through every page, unless he wants to. But I'll represent that's a copy of what was supplied to me.
MR. ANDERSON: Right.
MR. THOMAS: I'm trying to just get it identified as best we can.
MR. ANDERSON: Right. I'm just saying he's leafing through it to do the best he can without taking every page and looking at it in detail.
A. It appears to be complete.
BY MR. THOMAS:
Q. Okay. Dr. Jordi, how do you charge for your time?
A. I bill hourly.

Page 9

Q. And what is your hourly rate?
A. 350 an hour.
Q. Is your hourly rate the same for whatever work that you do?
A. Yes.
Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report?
A. We'd have to look at the receipts, the billings for that.
Q. Do you have those with you today?
A. I believe we do.
MR. ANDERSON: Yes.
BY MR. THOMAS:
Q. And the same for the Batiste matter?
A. Same.
MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes.
MR. ANDERSON: Sure.
BY MR. THOMAS:
Q. Those billing records are readily available, and you can determine how much it cost you to produce Exhibit 1, the report in Carolyn Lewis, and Exhibit 2, the report for Linda Batiste?

Page 10

A. I don't know if this has been billed yet, but this one should be. I think we bill monthly, so it hasn't gone out yet.
Q. When you say "this one," you're referring to Exhibit 2, which is Linda Batiste?
A. Yes, sir.
Q. Okay. And do you have records that you'd be able to get sometime during the day so that I can tell how much time you have into it that hasn't been billed so I know how much cost there was for the Linda Batiste report?
MR. ANDERSON: I might be able to help you. In response to your notice of subpoena, the 21 categories, we did our best to try to respond to those, the ones that we thought he could respond to, and as part of that we tried to get as up to date a billing as we could for you, and that would include as much of Batiste as possible, at least up until last week.
MR. THOMAS: Okay.
MR. ANDERSON: So that's -- we've tried. And I think that you'll be able to look at it, and from the dates be able to tell whether or not it includes anything this week or not.

Page 11

MR. THOMAS: Perfect.
BY MR. THOMAS:
Q. For the Carolyn Lewis case, your final report in Exhibit Number 1, is that a complete copy of the report of the opinions that you intend to give in the Carolyn Lewis case?
A. It is.
Q. Do you have any intention of doing any additional work prior to testifying in trial in this case in connection with new opinions for the Carolyn Lewis case?
MR. ANDERSON: I'm just going to object, because as counsel knows, we have a right to do rebuttal reports in this case, so he may not even understand that. And so with that caveat, that as he sits here today.
A. To my knowledge, this is complete, and this is what I will be using.
BY MR. THOMAS:
Q. Same question with respect to Linda Batiste, Exhibit Number 2; does Exhibit Number 2 represent a complete report of the opinions that you're prepared to give in the Linda Batiste case?
A. Yes.

Page 12

Q. All right. Do you understand that there are different products that are at issue in the Lewis case and the Batiste case?
MR. ANDERSON: Objection.
Go ahead.
A. The samples that I received I just received and ran by identification numbers without regards to -- certainly the pristine materials were identified.
BY MR. THOMAS:
Q. Okay. Do you have any knowledge -- what I'm trying to get at, Doctor, is, I'll represent to you, my understanding anyway, is the Carolyn Lewis case involves a product known as a TVT Classic or a TVT Retropubic, and the Batiste case, Exhibit Number 2, I understand, involves a product known as a TVT Obturator or TVT-O.
Do you know that?
A. No. That wasn't represented to us, as far as I'm concerned.
Q. As far as you're concerned --
A. It's an explant.
Q. Okay. In the work that you did in these matters, does it concern you at all

Page 13

whether this is a TVT Classic or a TVT Obturator or a TVT Retropubic or TVT-O?
A. No. They're all polypropylene, and in that sense, for that reason, no.
Q. Is it fair to understand, Doctor -- just trying to do something to make this easier, believe it or not -- is it fair to understand, Doctor, that the work that you did in analyzing the mesh explants and the mesh controls that's represented in Exhibit Number 1 and Exhibit Number 2 do not depend on the type of product that you were analyzing?
MR. ANDERSON: Objection.
Go ahead.
A. As a polymer chemist and having studied polypropylene, among others, for my lifetime of work, basically polypropylene is polypropylene is polypropylene, so it's going to -- if it's polypropylene it's going to have the characteristic reactions of polypropylene.
BY MR. THOMAS:
Q. Did the work that you did for Exhibit Number 1 differ from the work that you did in Exhibit Number 2 because of the name of the product that was analyzed in each case?

Page 14

A. Did not.
I'm sorry.
MR. ANDERSON: Go ahead. That's fine.
BY MR. THOMAS:
Q. And what were you trying to do when you -- what were you asked to do in Exhibit Number 1?
A. We were asked to compare pristine mesh samples and explant samples and determine whether or not there were differences; and if there were, what they were.
Q. What did you understand to be the differences that you were looking for?
A. I wasn't told to look for any specific differences. I was told to look for differences, if there were any.
Q. And how did you set out to determine whether there were differences between the explants and the pristine samples that you'd received?
A. Given the knowledge that it was polypropylene, classic tests that we would typically run on any polypropylene would be molecular weight, to see if it degraded in terms of its molecular weight.

Page 15

We would look for additive content, because that stabilizes polypropylene.
How am I doing speed-wise?
So we did additives analysis.
We would do DSC to look for crystallinity.
We did SEM to look for cracks.
We did SEM-EDX to look for elemental composition. Specifically we were looking for differing oxygen levels which would indicate and correlate with oxidation, if present.
We did FTIR analysis to look for presence of carbonyls. And we specifically there wanted to find out whether the flaking material, once we saw it from the SEM, was polypropylene or not, what was the composition, chemical composition of the flakes that were coming off the polypropylene fibers. I'm trying to think.
So we also ran PYMS. That's another technique to look for additives, presence of additives.
I need to --
MR. ANDERSON: Do you want to reference your report?

Page 16

BY MR. THOMAS:
Q. Absolutely.
A. Do I need to reference this one, because it's not marked?
MR. ANDERSON: You can look at anything.
A. It's this. I just want to make sure I have all of the techniques referenced here that I did.
We did optical microscopy as well to see if there were any obvious differences, and to just look at the shape of the fibers.
GPC. I think we got them all.
MR. ANDERSON: Did you say GPC?
A. Gel permeation chromatography. GPC for molecular weight.
BY MR. THOMAS:
Q. How did you determine what tests to conduct on the mesh that you analyzed in Exhibit Number 1?
A. I've analyzed these kinds of materials since 1980. In this particular business we built -- I founded this company, and so it's just years and years of experience. Polypropylene has to be stabilized because it's

Page 17

a reactive polymer. That information goes back at least to the '60s. So you've got to look for the antioxidants, the presence or lack thereof. GPC is to determine the molecular weight, as I said. DSC is to determine the melt point and the FLP at melt, which correlates with percent crystallinity. SEM is a means of looking at the physical shape of the fibers. So these are just standard techniques that we used. So we chose standard techniques that I would use for any such type of analysis.
Q. Type of such analysis, what do you mean by that?
A. Well, in our company we analyze any kind of polymer. So we analyze polystyrene one day, we analyze contact lens materials another day, we analyze polypropylene, some of which have been implanted in the human bodies, hips and so on on another day. You could really call us a materials lab.
Q. Okay. What I'm trying to understand is when you got this request from Mr. Anderson and his associates and they asked you to analyze this polypropylene material both as an explant and as a pristine sample, did you go to the

Page 18

shelf and pull off a list and say "I'm going to do this list of tests"?
A. No, because I already knew it from experience.
Q. Okay.
A. We would do this type of work for any client.
Q. So the tests that you identified for purposes of your report in both Exhibits 1 and Exhibits 2 are based upon your training, education, and experience, as opposed to any reference guide that you may have looked to to determine what tests you may have run, is that fair?
A. Well, I have reference guides. I mean I have books. I do continue to -- reading is an ongoing learning technique I continue to use, and always will.
Q. Sure.
A. But no, I wouldn't need to read those books to pop up with the techniques because they're standard in the industry.
Q. Is there a place where I could go to -- if they came to me and said "Mr. Thomas, I want to have these polypropylene tests run on

Page 19

this pristine control and this explant, what tests should I run?" Is there a place where you could direct me to figure out what would be the appropriate tests to identify the differences between the explants and the controls?
MR. ANDERSON: Objection as to form.
Go ahead.
A. There's probably chapters like that, books on chemical analysis that would suggest methodologies.
Generally you have a body of experience developed over many years, you just -- at this point in my life, I would know that I need to look up additives, for example, but then I would go to the Dr. Müller text which is in our reference list to look up how additives were used in various materials, and I would look under polypropylene, and I would find what additives are typically used for polypropylene specifically. So I'd know what to look for.
BY MR. THOMAS:
Q. And you're referring to a text cited in your report by a Dr. Müller?
A. Dr. Müller, Society of Plastics

Page 20

Engineers, yes.
Q. And for what purpose do you cite Dr. Müller, is that the additives analysis?
A. There would be additives analysis, stabilization of various polymers, polypropylene being one of them.
Q. Are there any other texts or authorities upon which you rely to identify the tests that you need to contact on the explants and the pristine samples?
A. To identify the tests needed?
Q. Yes.
A. Well, reading 400 pages of literature, and part of it is just the body of knowledge that you get from reading all of the literature. Everyone in the last -- starting back -- going back to the '60s has used these techniques.
Q. Okay.
A. Some of them, of course, are more modern today, obviously, than they were in the '60s. Today we have available FTIR microscopy, which we can look at a tiny sample. We didn't have that available them. LCMS didn't exist in the '70s and '60s, does now. So some of these techniques have come along in terms of

Page 21

development that are available today that weren't available prior times. But, again, today it's just -- every paper you read they use -- we use some of the same methods. LCMS is one of the bright and shining stars today that's come -- really come on strong in the last 20 years, 10 to 20 years.
Q. Real simple question, hopefully it's a simple answer.
Can you direct me to any authority, textbook, article, whatever you use in your business and in your expertise, that would identify the tests that you would do to detect the differences between an explanted piece of polypropylene mesh and a pristine control of the mesh?
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
A. I don't know of any such text that just has a single page where it lists -- if I want to know about thermal methods, I'd go to Edith Turi that I've cited. If I want to know about GPC, I'd go to Modern GPC chromatography text that I have. I have all these individual.

Page 22

And if you go to -- Odiam, for example, would be another one that's a common text that's used in polymer chemistry training sessions at like University of Connecticut where my son got his doctorate, he took -- he used that text. In that text you will see a chapter on DSC, you will see a chapter on GPC, you'll see a chapter on IR, you'll see all these various techniques.

But it might not include every one I used. I don't know that I can say -- I don't think I can say there's any one book that has every single method in it necessarily.

Q. Is it fair to understand, Doctor, that each of these tests that you ran were designed to detect any differences between the control sample of the mesh and the explant sample of the mesh?

A. That was the entire intent of the proceeding, as far as I understood it. It was just to look for differences, if there were any.

Q. Okay. What is degradation?

A. Well, degradation would be the loss of functionalness of, in this case, a polymer for its intended purpose.

Page 23

Q. Okay.

A. That could include things like oxidation, or environmental stress cracking. It could include mechanical degradation. For example, when products are -- waste materials in the manufacturing process are re-used, they make pellets out of the re-used material and they call it regrind, and each regrind cycle tends to degrade the polymer, so that's a type of degradation.

Q. Other than degradation as you've just defined it, did you look for any other differences in the polymer in the control sample as compared to the polymer in the explant?

A. Can I have the question repeated, please?

Q. Sure.

Other than the degradation as you've just defined it, did you look for any differences -- I'm going to change the question because I'm going to use a different term.

Other than degradation as you've just defined it, did you look for any differences in the polypropylene in the control sample as compared to the polypropylene in the explant

Page 24

that you analyzed?

A. Well, SEM would be certainly a major methodology. It gives you a visual observation of -- I'd have to add SEM to the term degradation, but it's a visual measurement as opposed to a chemical measurement.

Q. Okay.

A. But it makes it very obvious if something is degrading or not.

Q. Other than degradation as you have just defined it, and the SEM visual observations that you've just described, did you look for any other differences between the polypropylene in the control samples and the polypropylene in the explanted mesh?

A. I'm not sure I understand how to answer that question. We looked for differences which included all the tests that we've discussed; the molecular weight analysis, the additives.

Q. Don't all -- my question is; all the tests that you ran are designed to determine the extent to which the polypropylene degraded, is that fair?

A. Or could degrade. For example, if

Page 25

additives, antioxidants come out of the polypropylene, initially it may not be degraded, so I can't say that's degradation in and of itself.

However, once the antioxidants are out of the polypropylene, it is now vulnerable to oxidation. So it's a very valid technique in predicting the longevity, the functionalness of the product.

Q. Okay. So can we define it this way; that the tests that you ran, as you've just identified them, were designed to determine the extent to which the polypropylene in the explanted mesh had degraded as compared to the control, and the extent to which it might degrade in the future?

A. I like that better.

Yes.

Q. Okay. And you named three kinds, you named oxidation, environmental stress cracking, and mechanical degradation, is that fair?

A. That's correct.

Q. Your paper, your report discusses a bunch of other types of degradation. Can we focus on these three as being those types of

Page 26

degradation at which you looked for purposes of both Lewis and Batiste?
A. Well, right. You would have -- you could have UV light degradation, but that wouldn't be applicable to this case.
Q. The answer to my question, can we limit our questions in this case to oxidation, environmental stress cracking, mechanical degradation, and the SEM visual analysis of these meshes?
MR. ANDERSON: Objection.
Go ahead.
A. Well, I want to be able to include FTIR, for example.
BY MR. THOMAS:
Q. But FTIR is designed to discuss --
A. Show oxidation.
Q. Right.
A. I think we're in pretty good shape there.
Q. Okay. All I'm trying to do is make this shorter instead of longer. And so I'm not trying to trick you at all, believe it or not.
All right. So you received -- first of all, who hired you in this case?

Page 27

A. Mr. Anderson.
Q. And you've already described what Mr. Anderson asked you to do. And you determined on your own what battery of tests to conduct in order to evaluate the control mesh against the explanted mesh, correct?
A. That's correct.
Q. When you received the samples that you were to compare, I'm talking about the control samples and the mesh explant samples, how did you determine how to prepare those samples for testing?
MR. ANDERSON: Objection.
Do you want to talk about the control or the mesh?
MR. THOMAS: Both.
MR. ANDERSON: Okay.
MR. THOMAS: I'll do it first.
BY MR. THOMAS:
Q. How did you determine how to prepare your control samples for testing?
A. Well, with the control samples we had more material, boxes came in, and we had pictures in here of the process. I think that may be the best place to do, is just go look at

Page 28

the --
(Witness reviewing documents.)
A. So the control samples were received for analysis in sealed packaging.
BY MR. THOMAS:
Q. My question is pretty simple, I think. Maybe it's not. Page 12, you talk about sample preparation.
A. Right.
Q. Where did you go to determine how to prepare your sample for preparation for your analysis? Did you consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you're going to do?
A. Well, in the case with polymers like this, we have a balance area, we have a standard area with an optical microscope, and we have scalpels, and we have tweezers, and disposable scalpels, and aseptic tweezers, that's just our SOP.
And so we would cut the samples, cut off little pieces for various -- because different methods require different amounts of sample.

Page 29

Q. Did you rely on your own internal standard operating procedures for your sample preparations for the tests that you conducted?
A. Yes.
Q. Are the standard operating procedures that you have for Jordi Labs to conduct this analysis in writing?
A. Most of them are, yes. As far as -- I don't know if we have an SOP, I have to check on that, for actual cutting of the samples.
MR. ANDERSON: He just said "preparation." So I'm not sure --
THE WITNESS: That is preparation, yes.
MR. ANDERSON: Fair enough.
BY MR. THOMAS:
Q. And how would you describe the standard operating procedures for Jordi Labs, if I wanted to identify them to get them at a later time, that you did for sample preparation?
A. I don't know if we have a written for sample preparation as far as just cutting the samples. We have SOPs like for GPC, how to dissolve the samples, FTIR, how it's put on the instrument for each of those techniques, once

Page 30

the samples are passed to each specific analyst. But as far as -- I have a whole pile of SOPs over here for you for each of those methods.

Q. Okay. Probably what I'll do during lunch.

MR. ANDERSON: That's why the question is a little tough. When you're saying sample preparation, there's all these different tests that were done, so the question embodies a lot of things. I didn't want to keep objecting.

MR. THOMAS: I appreciate that.

BY MR. THOMAS:

Q. On Page 12 of your report, under "Sample Preparation," you discuss a "Control Experiment." It says "The control samples were also used as part of a control experiment designed to provide an indication as to the effects of formalin storage."

Why did you conduct a control experiment designed to provide indication as to the effects of formalin storage?

A. The samples received from Steelgate came informally, they were shipped to us that way, and we wanted to know what effect formalin would have on pristine polypropylene, or not, as

Page 31

the case might be, so we wanted to rule out any potential oxidation caused by formalin of the explants that were slipped to us, so we tried the controls the same way.

Q. What is it about formalin that caused you to be concerned about potential oxidation to the mesh?

A. Nothing specifically. It's just good lab practice to make sure that you treat -- if I want to compare a pristine mesh with an explant, I want the pristine mesh that I'm calling a standard to be treated identically, period, as much as I possibly can control it, to the explant material. Since the explant was in formalin, it's wise to put your control in formalin so they're treated identically. So any differences then seen can't be attributed to the formalin treatment, if there was any. I didn't know there was or not. But that is just good lab practice to me.

Q. As a biochemist, are you aware of any chemical reaction issues associated between formalin and polypropylene that may affect the chemical properties of polypropylene?

A. In general, no.

Page 32

Q. Continuing on Page 12, you discuss taking a sample of each control material, about 100 milligrams, placing it in formalin, 90 milliliters and heat it at 60 degrees centigrade for 48 hours. "In my experience, this temperature would be expected to provide an accelerated rate of aging and is consistent with other published methods for this purpose."

What does that mean?

A. Well, the samples have been sitting in storage at Steelgate for some time, we don't know how long exactly, at least I don't. The -- so if it had been in Steelgate for a month, and we put it in formalin here for a day, it wouldn't be equivalent treatment. So to get it as close to being equivalent treatment as we could we tried to -- in effect, we tried to accelerate any potential aging by running it at -- like doing the storage at 60 for 48 hours, so it would be more like the treatment that it would have received for, say, a month, or whatever the time was, from Steelgate.

Q. You cite to two references for this process, it's the ASTM Standard D3045, and the Inoue paper, 1961, the Journal of Polymer

Page 33

Science on Page 13 of your report.

A. Correct.

Q. Do those two references support using 60 degrees centigrade for 48 hours to replicate the aging process of polymer controls?

A. Well, various methods are used. But in general the principle -- definitely supports the principle. Various temperatures and times are given for various polymers, and so this was just trying to follow the principles.

Q. What age of explants in formalin does 60 degrees centigrade for 48 hours for the controls represent?

A. As to age at room temperature, specifically I don't know.

Q. Okay. Why did you choose 60 degrees centigrade for 48 hours?

A. Because that was consistent with these two references that would be recommended. If it doesn't show -- the point being if it doesn't show up in this temperature in this amount of time, it likely isn't going to react.

Q. Okay. So is it fair to understand that the 60 degrees centigrade for 48 hours is not designed to reflect any specific time that

Page 34

the explants may have been in formalin, but designed to determine if the formalin would have any degradation on the controls at any time?
A. It was determined -- it was an attempt to determine if formalin would react with polypropylene.
Q. And what did your experiment conclude?
A. All the tests, SEM, and all the rest of the tests, FTIR, showed no change.
Q. So is it your conclusion from that analysis that formalin has no chemical impact on polypropylene?
A. That's correct.
Q. Have you done any research to determine the extent to which formalin has any impact on polypropylene?
A. No, I have not.
Q. Formalin is --
A. Other than the test.
MR. ANDERSON: What did you say?
A. Other than this test, of course.
BY MR. THOMAS:
Q. Formalin is a mixture of formaldehyde?
A. Yes.
Q. Did you do any research to determine

Page 35

the extent to which formaldehyde had any chemical impact on polypropylene?
A. Well, in all the published literature, I looked at all these articles, I read over 400 pages, various authors determined -- did various studies of explanted materials. Everybody in the world, as far as I can see, treats their samples with -- or essentially everyone uses formaldehyde as a preservative. If you didn't do that, you would allow for potential bacterial growth and things like that that might degrade the polymer.
Q. My question was different.
Dr. Jordi, did you do any research to determine the extent to which formaldehyde can have a chemical reaction with and degrade polypropylene?
A. No.
MR. ANDERSON: Objection.
BY MR. THOMAS:
Q. A minute ago you said that everyone uses formaldehyde to preserve their -- what?
A. Their explant samples.
Q. Okay. And do you have an understanding of why everyone uses formaldehyde

Page 36

to preserve their explant samples?
A. Because it's a preservative.
Q. When you say "preservative," does that have a chemical meaning to you?
A. It has a more of a biological meaning. The formaldehyde preserves tissue and preserves anything from anything that's in it, from bacterial growth which would degrade biological materials.
Q. Okay. You said two things there, as I heard it. I'm going to do the second one first.
You said it prevents bacterial growth. Tell me what that means, please.
A. Well, in tissue, if you have -- by itself it just will pick up bacteria from flies landing on it or just from the air, and then it will begin to degrade.
Q. Okay. So it would be the influence of the outside bacteria growing on the explant that may have an impact on the chemical composition of the explant, is that fair?
A. That's one piece of it. But another piece would be if there were bacteria in the tissue -- for example, if there were an infection in the mesh that was taken out, that

Page 37

would be bacteria, it could continue to grow as well. I can't sort that out.
Q. Okay. The other thing you said, as I wrote it down, is that formaldehyde preserves tissue.
How does formaldehyde preserve tissue?
A. It makes for an aseptic environment. Bacteria can't grow in it, so hence, there's no degradation.
Q. So it's actually consistent with your second point, and that is it arrests the development of bacteria to prevent any degradation of the explant, is that correct?
A. That's the intent, yes.
Q. Are you aware of any chemical reaction that formaldehyde has with proteins that may be on explants?
A. Absolutely. Formaldehyde is an aldehyde, and it will react with any things like amines. It can react with any other reactor group that typical aldehydes with react with.
Q. As a part of your analysis in this case, did you study the impact of formaldehydes on any proteins that may be on explanted meshes?
A. No, we did not.

Page 38

Q. Did you consider that issue at all in your analysis?
A. No.
Q. Doctor, you identified three types of degradation which you analyzed in connection with your work in Exhibits 1 and 2, and one was oxidation, the second was environmental stress cracking, and the third was mechanical degradation, correct?
A. Yes.
Q. What evidence in your testing for Exhibit 1 for the Lewis case did you find oxidation?
A. For that we're going to have to go to the report.
MR. ANDERSON: Anything you need to reference in your report you can reference it.
A. Well, the first thing we saw -- that we looked at was SEM, and then that's coupled with SEM-EDX, so we'll look at a couple SEM charts first.
Page 26 shows a typical explanted sample. Figure 16 shows transverse cracks of surface polypropylene.
BY MR. THOMAS:

Page 39

Q. Let me stop you there, if I can. Are you finished?
A. Yes.
Q. I don't want to interrupt you.
The surface cracking that you just described on the record, this is your visual observation that you talked about before that you believe is evidence of oxidation, is that correct?
A. This is visual evidence of either oxidation or environmental stress cracking, or both, and by itself it can't tell you the difference.
Q. Got you.
But it's strictly visual?
A. This one is visual, yes, sir.
Figure 22 is another good example.
Q. What page are we on, please?
A. 29. Flaking polypropylene pieces.
Q. Now, you can do whatever you want to, I'm looking for -- perhaps it would be easier this way. You don't have to do all the figures that talk about visual observations. What I'm looking for specifically is each type of oxidation that you found in your report, then

Page 40

I'll explore each of those in a little more detail rather than going through the report and finding each one.
Does that make sense?
MR. ANDERSON: Your question was all the evidence of oxidation, so that made it a little tougher.
MR. THOMAS: I'm sorry. I'm not very smart sometimes.
MR. ANDERSON: It's not about smart.
I think he wants a more general question to begin with, and then he'll go into the --
A. Well, SEM-EDX, for sample, showed -- SEM-EDX showed increased oxygen levels in the cracked region that we just talked about.
BY MR. THOMAS:
Q. Okay.
A. And you don't want to talk about figures at this point?
Q. No.
A. Just concepts?
Q. Exactly. Thank you.
A. All right. I'll try to do my best, sir.

Page 41

Q. You're doing fine.
A. DSC showed a decrease in the heat effusion, and a decrease in the melt temperature versus non-cracked material. That correlates with environmental stress cracking, because the Delta H at melt correlates with the amount or the percentage of crystallinity, and hence the percentage of amorphous materials, which allows things like cholesterol and cholesterol esters and fatty acids to get into the cracking.
FTIR microscopy dearly showed -- by using the microscopic version of FTIR, coupled, we were able to actually take IRs of each flaked piece, and this flaked piece clearly showed protein and polypropylene. And since the polypropylene bands are weaker than carbonyl bands, they're alkyl, absorbance bands versus carbonyl, this chart that I'm looking at of this particular flaked piece would be estimated to be about 75 percent or so polypropylene, maybe 25 percent protein.
Q. Okay.
A. Because they're both there.
Q. And just generally for now, we'll go specifically to those issues later.

Page 42

A. Okay. The molecular weight averages that were determined showed basically no difference between cracked samples and pristine.
Q. Help me there.
A. And formalin treated.
Q. That is not evidence of oxidation, is it, the fact that they're the same?
A. Are you asking only for evidence of oxidation?
Q. Correct.
A. Okay. We'll skip that.
Q. Just so we're clear --
A. Right.
Q. -- the molecular weight analysis you did is not consistent with oxidation?
A. In and of, and by itself it is not.
Q. Thank you.
A. PYMS showed generally a lack of -- or very great minimization of both Santonox R and lauryl thiodipropionate.
Q. Okay. And those are antioxidants?
A. Those are the two antioxidants that are in the formulation, in the recipe from Ethicon.
Q. Is it fair to understand, though, that

Page 43

the PYMS analysis does not show oxidation, but is part of your earlier analysis about potential future oxidation?
A. That's correct, it is. Okay.
Q. So the PYMS analysis itself does not show oxidation of the polypropylene in the explants?
A. It shows vulnerability to oxidation is what it shows.
Q. It does not show any oxidation in the explants?
A. In and of itself, no.
Q. Thank you.
Have we covered the basics on the oxidation?
A. I think so.
Q. For those places where you found evidence of oxidation, as you've just described and as reflected in your report, were you ever able to measure the extent of antioxidation of the explants that you analyzed?
MR. ANDERSON: Objection.
Go ahead.
A. Are you talking about quantitative numbers now?

Page 44

BY MR. THOMAS:
Q. Yes.
A. Generally the percentage of oxygen in oxidized polypropylene, at least initially, is in the low percent range. So it doesn't take very much increase in oxygen in polypropylene to cause embrittlement, rigidity, and those kind of effects. Those are caused by presence of ketones and aldehydes as the oxidation goes on, carboxylic acids if it goes far enough.
Q. Doctor, my question is a little more specific than that.
Did you attempt to measure the extent of oxidation in any of the mesh implants quantitatively?
A. It would be relative quantitation, comparing control versus explant.
Q. Did you express any measurement of oxidation in the explants compared to the controls in your report?
A. I'm sorry, can you repeat the question?
Q. Did you set forth any opinion as to the extent of oxidation from the explants measured quantitatively in your report?

Page 45

MR. ANDERSON: Objection.
Go ahead.
A. Again, it was a relative thing, so I don't know that I can say. It would be quantitative.
But, for example, pristine polypropylene didn't show any carbonyl to 1760, 1740 that we could see. But the explants did.
BY MR. THOMAS:
Q. Did you attempt to measure in that context the extent to which the carbonyl issue had any impact on the ability of the polypropylene to function for its intended purpose?
A. All oxidation is bad. It's a relative determination. So you would hope there wouldn't be any carbonyl observed, is what you would look for if the material is good.
Your question, I'm sorry.
Q. Might have been a bad question. Let me see if I can do it again.
In your analysis of oxidation, did you ever measure the extent to which the polypropylene in the explanted meshes was degraded in a quantitative way?

Page 46

A. In a relative quantitative way is all we did.
Q. And tell me what that means.
A. Well, that means if I have a peak for carbonyl, I have -- like if I had no peak in the pristine and I have a peak, a measurable peak in the explant, then I can say with certainty that the explanted material is more oxidized than the pristine.
Q. Are we talking about oxidation to the extent that it compromises the ability of the polymer to function for its intended purpose?
A. The only way I know to answer this is in science we would pool multiple methods. I have to look at the SEM photographs and look at the carbonyl levels and try to correlate the carbonyl with the degree of damage actually observed physically in the SEM. So that's the kind of thing what I mean by "relative."
Q. Do you have an opinion as you sit here today, based on your training, education, experience, and review of the materials in this case, of the extent to which the polypropylene in the mesh explants oxidized in the context of the loss of functionalness for its intended

Page 47

purpose?
A. Yes, I do.
Q. Okay. What is that opinion?
A. The material appears degraded, some of it severely degraded. There's a range from sample to sample. And in two cases of 23 samples that we ran, we didn't see any damage. 91 percent of the time we did.
Q. Are you talking now about your visual observations through the scanning electron microscopy?
A. Yes, correlating that, of course, with the carbonyls.
Q. I'm talking about the analysis that we -- strike that. Let me come back to that.
Doctor, let's go back to your sample preparation. That's what happens when I find rabbit holes.
What steps did you take to prepare the explants that you received for analysis?
MR. ANDERSON: Objection.
Go ahead.
A. Well, the samples were received at our receiving area, and then they were -- the boxes were photographed, and they were removed, and

Page 48

they were handed to the appropriate technician to do the sampling that's described in the photograph. They're removed -- now you're talking about the actual --
Q. Explants, correct.
A. -- explant.
Received tissue bundles.
Q. You're on page?
A. Now I'm on 16.
Q. Thank you.
A. And little pieces were cut off with disposable scalpel. And the picture on the right -- I'll wait for you to get there if you want.
Q. I'm fine. Go ahead.
A. Little pieces were cut off, and that's what was then repackaged in formalin for shipment for SEM.
Q. Okay. As we look on Page 16, there are four photos there in Figure 2. The top left photo in Figure 2 is the way that you received the sample?
A. Yes.
Q. Dumped out of container, is that fair?
MR. ANDERSON: Objection.

Page 49

A. Yes.
BY MR. THOMAS:
Q. I'm sorry, I'm trying to be casual. Excuse me. That was a bad question. Mr. Anderson is exactly right.
Dr. Jordi, is it fair to understand that the top left on Figure 16 reflects the samples as received before you did anything to them?
A. That's correct.
Q. And how did you separate the mesh in the lower left-hand corner in Figure 2 from the tissue that appears on the lower right-hand corner of Figure 2?
A. We utilized forceps to pull the tissue off of the sample. As you can see, in the left bottom picture there are little bits of tissue left.
Q. Who did that? Did you do that?
A. Adi Kulcarni. Took about an hour a sample.
Q. And did you use forceps in each hand, is that how you do that? Or how do you do that?
A. He just -- he has to hold it, he has to hold it while he pulls tissue off.

Page 50

Q. Hold it in his hand?
A. No. With forceps.
Q. So you've got the forceps?
A. Two, yes.
Q. Two forceps.
Is there a Jordi standard operating procedure about how to remove tissue from mesh?
A. No.
Q. How was it determined how to remove the tissue from the mesh?
A. Well, the technique was to remove the tissue touching the -- as little as possible the mesh itself so that you wouldn't cause any damage to it.
Q. Did you instruct this technician -- is that the right word?
A. No. He's a Ph.D.
Q. Did you instruct -- what's his name again? I'm sorry.
A. Adi Kulcarni.
Q. Did you instruct Dr. Kulcarni on the method to separate the mesh from this tissue?
A. No, I did not.
Q. Do you know what procedure he followed or what -- strike that.

Page 51

Do you know what methodology he followed in order to protect the integrity of the mesh and the tissue as he separated the two?
A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work area to begin with, and used aseptic forceps.
Q. Is there a standard methodology, of which you're aware, that tells Dr. Kulcarni how to properly separate the mesh from the tissue?
A. I don't think so. I don't think one exists. I've never seen one.
Q. Did you discuss with Dr. Kulcarni how to appropriately separate the mesh and tissue?
A. Did I discuss with him how to do it?
Q. Yes.
A. We discussed -- yes, we had discussions. But, you know, he is a very, very careful worker.
Q. What was the purpose of your discussions with Dr. Kulcarni about how to separate the tissue from the mesh?
A. I wanted to see the samples for myself. That's all.
Q. Did you have any discussions with

Page 52

Dr. Kulcarni about the methodology to separate the tissue from the mesh?
A. No. It appeared very gentle, as good as we could possibly do.
Q. Okay. Other than separating the tissue from the mesh, as you've just described in Figure 2 on Page 16 of your report, which is Exhibit Number 1, were there any efforts made to otherwise treat the mesh prior to testing?
A. No.
Q. For the tissue sample that appears in the upper left of Figure 2 on Page 16, was there any discussion about trying to clean that sample?
A. Well, that's what we've just been discussing. This was how it was cleaned, it was done with forceps.
Q. Okay. At any time was there a discussion with Dr. Kulcarni about cleaning the mesh that was removed from the tissue to remove proteinaceous material from the mesh?
A. No.
Q. Is it fair to understand, Dr. Jordi, that the mesh that appears on Page 16 in the lower left-hand corner is mesh that has been

Page 53

separated from the tissue without further cleaning?
A. That's correct.
Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to -- strike that.
Did you ever consider cleaning the mesh that was separated from the tissue prior to conducting your tests that you did in Exhibit 1?
A. At the time this work was done, no.
Q. Before you did your work in Exhibits 1 and 2, did you do any research into analysis by other scientists in the methodology for testing explanted meshes?
A. I did.
Q. And what research did you do?
A. I read a number of articles, Clavé and others.
Q. You read Costello?
A. Costello.
Q. Did you read de Tayrac?
A. Yes.
Q. Before you did your testing in this case?
A. No. It's recent.

Page 54

(Whereupon, Jordi Exhibit Number 3, de Tayrac and Letouzey article titled "Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery, was marked for identification.)

A. Are you going to de Tayrac?

BY MR. THOMAS:

Q. Yes.

Let me show you what I marked as deposition Exhibit Number 3. You have Exhibit Number 3 in the materials that you brought with you today?

A. Yes, I do. I'm looking for it. Here it is right here, de Tayrac.

Q. When did you obtain your copy of Exhibit Number 3, which is an article published in the -- by Renaud de Tayrac and Vincent Letouzey, it appears in International Urogynecology Journal in 2011? When did you first receive that?

A. I don't recall exactly, because I receive so many articles. I remember reading it fairly recently, within the last two weeks.

Q. Did you have a chance to review

Page 55

Exhibit 3 prior to the time that you conducted your work in Exhibits 1 and 2?

A. No.

Q. If you turn to Page 778 of Exhibit 3, read as much as you need to.

A. 778?

Q. That's right. You're on the right page.

A. This is 780 in mine.

MR. ANDERSON: Top right.

A. Got it. Top left.

MR. ANDERSON: Top left, yes.

A. All right.

MR. ANDERSON: After you finish de Tayrac, can we take a break?

MR. THOMAS: Sure. Take a break right now if you'd like to.

MR. ANDERSON: Sure.

MR. THOMAS: Let's do that.

(Whereupon, a recess was taken from 10:13 a.m. to 10:25 o'clock a.m.)

BY MR. THOMAS:

Q. Let's go back and make this more clear. Go to Page 16 of your report.

On Page 16 of your report on Figure 2

Page 56

in the lower left-hand corner you have the mesh separated from the tissue, correct?

A. Correct.

Q. And you understand when the mesh is in the body -- was in the body it was surrounded by materials in the body?

A. That's right.

Q. Including proteins?

A. And those materials are shown in the bottom right picture. That is the material removed.

Q. Okay. Is it your opinion that after the mesh is separated from the tissue that there's no longer any protein material on the mesh?

A. No, I believe there still is some protein on the mesh. We can see it, we can see tissue, bits and pieces.

Q. All right. Are you familiar with the term known as biofilm?

A. Yes.

Q. What do you understand a biofilm to be?

A. Well, biofilm would be a covering material that coats things in the body. As far

Page 57

as its chemical composition, I've never seen it described in these papers that I've read any more than to say biofilm. But obviously protein, probably glycoproteins.

Q. Would you expect a biofilm to surround the mesh that is in the explant samples that you analyzed?

MR. ANDERSON: Objection.

Go ahead.

A. I think that's a very distinct possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM.

BY MR. THOMAS:

Q. All right. Did you make any effort in your sample preparation as reflected on Page 16 of Exhibit Number 1 to remove all protein materials or biofilms from the mesh before analysis?

A. No, we did not. We didn't want to take tremendous efforts in -- effort is not the right word. But we didn't want to do anything that would try to disturb the mesh.

So for SEM, for example, looking at the upper right picture, we cut a piece of

Page 58

tissue off, and the SEM was actually taken on the fibers imbedded in the tissue so that we didn't have to pull the fibers out. Because we were afraid that with forceps we might cause scarring of the surface, and we didn't want to cause anything like that if we could avoid it. So that was done to -- we didn't even remove the tissue in that case for the SEM work, because we didn't want to risk injuring the fibers.

Now, we had to get the fibers clear to do DSC, FTIR, GPC, so that's why the tissue was removed for those studies.

Q. You are aware that using forceps to separate the tissue from the mesh can impact the physical integrity of the mesh?

MR. ANDERSON: Objection.

Go ahead.

A. We were very gentle in how we did this, and it's described in our procedure. We tried every way we possibly could to take great care to not disturb the mesh. So with forceps we could grab two pieces of tissue and not ever touch the mesh to pull it apart.

BY MR. THOMAS:

Q. Okay. But you made no further effort

Page 59

to clean the mesh to remove any protein or biofilm that remained after removing the mesh with the forceps, correct?

A. Correct.

Q. Now, you've now read de Tayrac, and de Tayrac analyzes the results that Clavé found in his study, correct?

A. That's correct.

Q. And they state on Page 778, "We also experimentally tested Clavé's conclusion regarding a correlation between infection and polypropylene 'degradation'."

A. Where are you, sir?

Q. The very first, Page 778.

A. 778.

Q. "Using the same method of mesh infection, we also experimentally tested Clavé's conclusion regarding a correlation between infection and polypropylene 'degradation'."

And what de Tayrac did was they washed their mesh with dimethyl sulfoxide and used ultrasonic shock, and then analyzed the explanted mesh by electron scanning microscope, correct?

A. Correct.

Page 60

Q. And de Tayrac finds that the degradation is due to the biofilm, correct?

A. That's what the paper says.

Q. Do you disagree with that?

A. I do.

Q. Why?

A. It's best showing you in my picture. Can I show you a figure?

Q. Okay.

A. Go to the FTIR section of my report, I'll give you a page here in a minute, Page 71, for example. There's a number of pages. 71 is as good as any, I guess.

There's protein here, and as evidenced by the 1653, the 1531, amide 1, and amide 2 bands. But there's also polypropylene, 1445, 1377, and then the four little atactic bands that are shown to the right of the 1377 band. And since the alkyl bands are less intense than the carbonyl bands of the protein, or any other carbonyl types, this would be about a 75 percent polypropylene, give or take a little, and maybe 25 percent protein, or what you would call biofilm.

So this is the stuff that they

Page 61

actually removed with their dimethyl sulfoxide their sonication treatment, so it was already gone.

But what we did was we actually rolled one of the fibers, and then took the pieces that came off, the same pieces they got off in their Figure 1 shown in section B here, Figure 1, we ran the infrared of the pieces that actually came off, and it wasn't biofilm, it was polypropylene.

Q. Dr. Jordi, do you find any methodological flaw in de Tayrac's decision to wash the explants used in his experiment with dimethyl sulfoxide and using ultrasonic shock?

A. If you have -- I certainly do. If you take a material that's cracked and crazed as we saw in our SEMs, and as he shows here in his Figure A on Page 778, that material is going to be very susceptible to flaking off.

When I look at 778, Figure A, I see what probably is biofilm looking like that cloud material on top of the polypropylene, and the polypropylene underlying it, which was then blown off. Ultrasonic treatment is kind of -- is a shock treatment, and it's like putting a

Page 62

bomb on the polypropylene fiber, so it's going to shake off anything that's loose, which it did very beautifully, we know that's what it does, and it did a beautiful job.

Unfortunately, the stuff that came off wasn't biofilm, are at least it wasn't totally biofilm, it wasn't even 50 percent, the majority of it was polypropylene. At least in my case. I can't speak to their -- without actually doing the IR of the flaked materials in theirs, I can't tell you a percentage, or even an estimate.

If they had run an IR, which they didn't do -- I'd like to know why they didn't run an IR to see what it was, they just state that it's biofilm with no proof.

Q. Have you attempted to clean a mesh explant and run the same tests that you ran in Exhibit 1 and Exhibit 2 to determine if your findings are consistent with cleaned explanted mesh?

A. Cleaned how?

Q. Let me ask it this way.

Is there a way in your training, education, and experience to clean the mesh and

Page 63

remove biofilms and proteins to allow for the analysis of the explanted mesh as cleaned?

A. Yes, there is. I've become aware of this since this original work was done. It's sodium hypochlorite.

Q. And tell me how you use sodium hypochlorite to clean proteins or mesh before you do the analysis?

A. You just soak the sample, the fiber mesh in this case, in the typically 13 percent chlorine solution of sodium hypochlorite.

Q. Have you done that?

A. We did not do that in this work.

Q. Have you done that at any other time?

A. No. Not at this point we haven't.

Q. Have you ever gone -- strike that.

Have you ever tried to replicate -- start over one more time.

Dr. Jordi, have you ever tried to take an explanted mesh, remove biofilm or other protein material, and test it to see the extent to which it had degraded?

A. I really didn't need to do that in this case because the SEM photographs were so clear.

Page 64

Q. My question is; have you ever done that?

A. No, not to this point.

Q. And is there any reason other than the FTIR analysis that you've just described on Page 71 and other places in your report --

A. Correct.

Q. -- that supports your opinion that de Tayrac is wrong?

MR. ANDERSON: Objection to form. Go ahead.

A. I think the infrared speaks for itself. It's -- in my view as a chemist, a polymer chemist, it's pretty locked tight. You can't get polypropylene infrared bands if polypropylene isn't there.

BY MR. THOMAS:

Q. Is that the -- my question is simple. Is that the only information that you have, based on your analysis and work on this case, that confirms for you that de Tayrac is wrong?

MR. ANDERSON: Objection.

A. That de Tayrac is wrong. I think I would say yes. I mean we do have other evidence like DSC perhaps, but we have to -- that wasn't

Page 65

run here either, so I have no data from the paper with which to judge the question.

BY MR. THOMAS:

Q. You rely on the FTIR analysis in your report in Exhibit Number 1 and Exhibit Number 2 in support of your belief that de Tayrac's conclusion that what is seen in the SEM is biofilm to be incorrect, is that fair?

A. That's fair.

Q. Back to oxidation.

Do you have an opinion about what caused the oxidation that you've identified in your report?

A. I believe there was two major reasons.

One was lack of antioxidant, making the polypropylene vulnerable to attack by hydrogen peroxide and other things, from macrophages and so on in the body.

And the other was environmental stress cracking, which DSC suggests because of the decrease in the Delta H at melt, and the increase in amorphous content of certain of the polymers, and what seems to happen is some samples seem to have a mix of both, and some would be a preponderance of environmental stress

Page 66

cracking and other damage, and another would be caused by classical oxidation mechanism. And the majority of samples in this case seemed to have both. But it's possible to have just one or the other as well.

Q. Do you have an opinion as to whether the polypropylene in the Ethicon mesh -- strike that.

What is it about the human body, the biochemistry of the human body, that causes the antioxidants to be depleted from the mesh?

MR. ANDERSON: Objection.

Go ahead.

A. I don't know if that's the right question. If I can explain?

BY MR. THOMAS:

Q. Please.

A. If I were to put polypropylene mesh in a solvent like methylene chloride or ethanol or propanol or methanol, or any organic solvent, the antioxidants would bleed out at a certain rate. And the problem here is the mesh is fine, so it's a relatively small-ish diameter so there's not a lot of distance from the internal part of the fiber to the surface. So if I put

Page 67

it in solvent, it's going to bleed out. If I put it in the body which is full of lipids, cholesterol, phospholipids, cholesterol, cholesterol esters, fatty acids, it's going to be bleeding out there. But it would bleed out in either place. It's not really a phenomenon I see that's unique to the human body, it would happen either place, and so it just bleeds out because of the high -- relative high surface area and small diameter.

Q. Do you have an opinion of what specifically it is about the human body that causes the Ethicon polypropylene mesh to leak, leach its antioxidants?

A. I don't think -- as I say, I don't think that is the right question. It's going to leach wherever it is in any solvent.

It wouldn't leach in water, obviously, because it's not soluble, or not wetted by water. But anything that will wet it, whether it's a fatty acid or whether it's a solvent, fatty acid in the body or a solvent, is going to cause it to remove, I guess, the fatty -- the antioxidants that are bleeding to the surface.

Q. Let me ask it this way.

Page 68

Doctor, do you have an opinion as to what substances in the human body cause the Ethicon polypropylene mesh to lose the antioxidants that you've identified in your report?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

A. It just bleeds, it bleeds out because of the nature of the -- we call it blooming in the industry. Materials leach out of the polymers that they're in, even in air to some degree, and then they come on the surface and get wiped away. So this would be a slow process, which is why I believe the papers typically show no initial oxidation. It has to be in the body for a while before you see the major amounts of these effects.

BY MR. THOMAS:

Q. How long?

A. Some of the papers say three months.

Q. Do you have an opinion about how long a mesh has to be in the body before the antioxidants are depleted to the point where the mesh can degrade?

Page 69

A. No, we would have to do a study, a time study to answer that question, where we actually measured -- right now we've just measured levels of antioxidant in the samples received, the explants and the controls. We would have to do a time study to answer that question where we'd do three months, six months, nine months, a year, five years, however long we wanted to do the study, and measure the amount of the two antioxidants present as a function of time.

Q. Is the sole basis for your opinion that the Ethicon polypropylene mesh at issue in this litigation leaches its antioxidants the testing that's reflected in Exhibits 1 and 2?

A. Yes.

Q. A moment ago I asked you about the causes, I think, of degradation, and you said oxidation in combination with, in some instances, environmental stress cracking?

A. Correct.

Q. We also talked earlier about mechanical degradation. Is there any evidence of mechanical degradation in your work in either Exhibits 1 and 2?

Page 70

A. No. That's a minor player here. If any effect, it would have to do during the manufacturing phase. When the polymer is put through the dye, it will be extruded under stress, that's mechanical force, and that will tend to sheer polymer chains and tend to degrade. But that's the only application. Certainly in the human body I don't see any major application of stress, mechanical stress.
Q. Okay. So can we confine our discussion today of degradation in terms of oxidation and environmental stress cracking?
A. I think so.
Q. Dr. Jordi, if the mesh antioxidant additives remained in the mesh, would the mesh be able to perform its function in the body without oxidizing?
A. I think that's suggested in the literature, yes.
Q. Okay. Do you agree with what the literature says, that is; if the mesh maintains its antioxidants that it's able to perform its function in the body as intended?
A. It certainly would -- I don't know that I can answer the question completely, but

Page 71

it certainly would increase the longevity of the product for sure.
Q. Okay. Do you have an opinion that the mesh with the antioxidants that stay there is unsafe for its intended purpose without more?
MR. ANDERSON: Objection as to form. Go ahead.
A. Without more?
BY MR. THOMAS:
Q. I'm just trying to narrow the scope here. I'm trying to understand. You've told me that the literature says that if the antioxidants do their job and stay in the mesh, that the mesh then is appropriate for use in the body to perform the function for which it's intended. Is that fair?
MR. ANDERSON: Objection. Mischaracterizes his testimony.
BY MR. THOMAS:
Q. You can answer it if you can.
MR. ANDERSON: Well, my objection stands. It mischaracterizes his testimony.
MR. THOMAS: I understand. You said it twice. Thank you.
MR. ANDERSON: Yes, I did.

Page 72

BY MR. THOMAS:
Q. What are you reading?
A. I am looking at -- I'm looking for a paper that shows the -- I don't know whether it's -- it's either Liebert or Turi, Oswald and Turi.
Q. I'll help you here a little bit.
(Whereupon, Jordi Exhibit Number 4, Liebert, et al study titled Subcutaneous Implants of Polypropylene Filaments, was marked for identification.)
BY MR. THOMAS:
Q. Let me show you what's been marked as Exhibit Number 4. Exhibit Number 4, is that the Liebert study to which you were just referring?
A. 1976, yes, I believe, yes.
Q. And in Liebert they studied meshes that had been treated with oxidants -- excuse me, treated with antioxidants and meshes that had not, correct?
A. Correct.
Q. And found that those that had been -- that had antioxidants added to them did not degrade like those that did not have

Page 73

antioxidants, correct?
A. That's right, showing that, yes.
Q. Is that the basis -- strike that.
Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist degradation?
A. Well, it's that, and it's my lifetime of experience analyzing polypropylenes, and when they degrade and when they don't.
Q. Do you agree with --
MR. ANDERSON: Are you through with your answer?
THE WITNESS: Not quite.
BY MR. THOMAS:
Q. I'm sorry.
A. I'm thinking. I'm sorry.
Q. You take all the time you need. Never meant to interrupt you.
A. I analyzed -- these are related, but they're all polypropylene, analyzed two other types of materials over my experience that I can recall.
One was a seating material at a stadium, that was involved in a stadium seating

Page 74

in Japan, 100,000 seat stadium. The seats in one year from installation turned to dust and blew away. So they had sent me some retains, and I had to analyze it, and the polypropylene was not stabilized. And so that's part of my lifetime of experience.

Another case, the client was suing a motorcycle manufacturer because -- for a defective gas tank. But he'd hit a brick wall at a very high rate of speed, I don't remember the exact, 75, 80 miles an hour, and the gas tank ruptured and exploded. And so they were blaming the manufacturer. So I had to analyze a bit of that. In that case the stabilizers were present. And the point was no gas tank is going to survive hitting a brick wall at 75, 80 miles an hour, so -- even though the stabilizer was there. So it wasn't degraded, molecular weight-wise, it wasn't degraded, the antioxidants were there.

And in the other case, it turned to dust and blew away, and the antioxidants were not present.

So when I see a lack of antioxidant in essentially basically all these samples, by both

Page 75

PYMS and LCMS, it tells me the polymer is exceedingly susceptible to oxidation by hydrogen peroxide, which it would be partially protected from if antioxidants were still there, but they're not there.

Q. Okay. Is it your opinion that hydrogen peroxide is the material that attacked the mesh that caused it to degrade as is reflected in Exhibits 1 and 2?

A. Well, in the body there are things like ferrous ion, for example, and if -- I can't answer the question with a simple answer because, again, there's multiple causes.

If there's any free ferrous ion around you'll get what's called a Fenton reaction, which converts hydrogen peroxide to hydroxyl radicals, which are more damaging than the hydrogen peroxide to begin with in causing degradation of the polypropylene. It's a free radical initiator step.

So if there is, you know, bleeding perhaps, that can be a source of iron, and if there's some ferrous ion around -- of course it has to be free ferrous ion, the body needs protein to bind iron, because it's dangerous in

Page 76

their free form. But the Fenton reaction is well-known.

Q. You call it the Fenton reaction?

A. Fenton reaction, yes.

Q. Okay. If hydrogen peroxide was the cause of the degradation of the polypropylene mesh, would there be a change in the molecular structure of polypropylene?

A. Repeat the question, please? I'm sorry.

Q. If the hydrogen peroxide that you described was the cause of the degradation in the polypropylene mesh, would there be a change in the chemical structure of the polypropylene mesh?

A. That's right, there would be.

Q. If there was a free radical that degraded the polypropylene mesh, would there be a change in the chemical construction of the polypropylene mesh?

A. Yes. You would be inserting oxygen into the chain in the form of either ketone, aldehyde, hydroxide.

Q. And the free ferrous ion which you referred to as the Fenton?

Page 77

A. It's not just a free -- if you would like I'll give you the reaction. Do you want that?

Q. Yes.

A. Fe2+ plus hydrogen peroxide goes to, an arrow, Fe3+ +HO- -- that's hydroxide, that's harmless, but here's the problem -- +HO., which is the radical, hydroxy radical, that is many more times damaging to polypropylene than the initial hydrogen peroxide.

Q. Okay.

A. Now, I can't sort out which one is --

Q. That's fine. You're consulting a paper there. What's the paper you're consulting?

A. "Mechanisms of polymer degradation in implantable devices" by Williams.

Q. That's David Williams?

A. David Williams.

Q. That's the one cited in your --

A. Yes, sir.

Q. Okay. The last reaction you described is called the Fenton reaction, is that right?

A. Right.

Q. Does the Fenton reaction causing

Page 78

degradation of polypropylene alter the chemical structure of the polypropylene?
A. Does the hydroxide -- or the Fenton reaction cause, is that what you're asking.
Q. Yes.
A. Sure it does, because that's the production of the hydroxy radicals which causes the actual change.
Q. Any other potential sources of oxidation to the polypropylene mesh given the leaching of antioxidants that you've described?
MR. ANDERSON: Objection as to form. Go ahead.
A. You could also have what's called a more general version of the Fenton reaction, would be the Haber-Weiss, H-A-B-E-R - W-E-I-S-S, reaction.
BY MR. THOMAS:
Q. Are you consulting the Williams article again?
A. Yes. That would be include cuprous ion as well as ferrous ion, could include titanium is another one, titanium 3 or vanadium 4 is another possibility. Those are not commonly found, we're not going to worry about

Page 79

those in the body.
Q. Titanium and vanadium aren't going to be found in the body, are they?
A. No. It's cuprous and ferrous.
Q. Are all of the potential methods of degradation for the polypropylene mesh that you've identified in the human body in the Williams article that you're consulting?
A. Well, they're certainly in there. Other authors describe that as well.
Q. Okay. Are there any other methods described by other authors?
A. Other methods?
Q. Yes. Have we covered all the bases in the Williams article?
A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also.
Q. How much heat would require --
A. I don't think the human body, we'd have to worry too much in the human body. We're talking processing now.
Q. How much heat does it take to degrade polypropylene, do you know?

Page 80

A. Those are described in actual tests in the Dr. Müller book, timed experiments.
Q. Do you know?
A. Well, it depends on the temperature. And it varies with the environment, the oxygen environment and the temperature actually used. Some are run at 200 degrees, some are run at 100 degrees.
Q. Do you know the temperature at which the polypropylene that's used in the Ethicon mesh will degrade?
A. I know in general terms that the higher the temperature, the faster it will degrade. That's what I know. Which is uniformly true.
Q. Do you have an opinion as you sit here today of the temperature at which the Ethicon mesh used in the TVT device will degrade?
A. Without testing, no. And it would depend on whether the antioxidants are there or not, that will affect the temperature.
Q. Is it possible to measure the amount of hydrogen peroxide that is in a person around the mesh implant?
A. We have techniques that will allow us

Page 81

to measure hydrogen peroxide. We have hydrogen peroxide test strips, for example, but you can't stick those into an implant very well. So I don't know, I've never seen it talked about or done anywhere.
Q. Are you able to test for the presence of hydrogen peroxide on the explants that you analyzed?
A. You could try to use those test strips and see if -- the strips turn blue if -- but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway.
Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh?
A. Well, no, I don't think so, not as received.
Q. You don't know, or you don't think you could?
A. You can't, because --
Q. I didn't hear you. I'm sorry. You

Page 82

cannot?
A. Cannot.
Q. Thank you.
A. Because it's not there, it's been treated with formaldehyde when we get it, so it's not the way it was in the body --
Q. Okay.
A. -- at the time of excision.
Q. So is it fair to understand that it's your opinion that you're not able to test these mesh explants for materials that may have been in the body that you believe caused or contributed to the degradation of the mesh?
MR. ANDERSON: Objection to form.
Materials in the body, or chemicals in the body?
MR. THOMAS: Thank you, Ben.
MR. ANDERSON: Just to be clear.
BY MR. THOMAS:
Q. Doctor, is it fair to understand it's your opinion that because of the placement of the explants in formaldehyde, that one is unable to test for chemicals in the body that may have caused or contributed to the degradation of the mesh?

Page 83

A. That question would require a lot of research. But it's possible, for example, that we could -- certainly we could look for iron in the tissue, or we could look for copper in the tissue, which would be consistent with the Haber-Weiss reaction, which would have produced the hydrogen peroxide in the first place. So we could see telltale signs. In that sense, we might be able to see something.
Q. Doctor, as you sit here today, is there a test that you know of that could be performed on these explanted meshes to determine which chemical substance in the body caused or contributed to any degradation of this mesh?
A. If it's hydrogen peroxide produced in the macrophages, we can't test for it because it's not there.
Q. Okay. Anything else?
A. If it's caused by the Fenton reaction or the Haber-Weiss, yes, we could take that tissue, and we could dissolve it, and then run ion chromatography and determine parts per billion levels of iron and the copper.
Q. What would that tell you?
A. It would tell us the potential levels

Page 84

of metals that would be the catalyst for the Haber-Weiss reaction or the Fenton reaction.
Q. If you had that information, how would you use that to determine the extent to which those chemicals caused or contributed to the degradation of the mesh?
A. Well, the greater the concentration of the iron and copper, copper 2 and iron -- copper 1 and iron 2, the greater the damage would be.
Q. Okay.
A. It should correlate. But it's complicated, because if those metals were tied up by the typical proteins in the body that are supposed to tie up copper and iron so they are not -- they don't kill us, you have to figure out a way to -- and as I sit here, this is just research, I'm unable to answer the question completely, I would have to be sure that the iron we determined was free ferrous ion in the body and free cuprous, or it wouldn't be damaging even if present.
Sorry, that's my answer.
Q. Okay. Let me see if I can finish this.
Is it fair to understand, Doctor, as

Page 85

you sit here today you don't know of a test that would enable you to determine which chemicals in the body caused or contributed to any degradation of the mesh explant samples?
A. No. We just know that macrophages have been shown to -- in superoxide and hydrogen peroxide.
Q. Okay. You said "no" to my question.
A. I'm sorry. Correct.
Q. Is it true, is it fair to say that, as you sit here today, that you don't know of any tests that would allow you to determine which chemicals in the body may have caused or contributed to any degradation of the mesh explant samples?
A. Again, from my reading the literature and seeing the production of hydrogen peroxide and superoxide, that has to be one of the mechanisms, and the other ones could be. I don't know how to answer the question.
Q. But the question is; it's fair to understand, as you sit here today, that you do not know of any test that you could perform to determine which chemicals in the body may have caused or contributed to any degradation of the

Page 86

polypropylene mesh in these explants? You don't know of one?
A. Seeing the oxidation, I couldn't tell you whether it was caused by the Fenton reaction, the Haber-Weiss reaction, or hydrogen peroxide, that's true, if that's what you want.
Q. Thank you.
Or any other substance, there's not a test that you can do to tell us what caused it?
A. No. All I can say is I'm looking at the fact of the degradation. It had to happen, so I'd be looking for -- as to what specifically caused it, I have to agree.
Q. Thank you.
A. I can't answer.
MR. THOMAS: We can take a quick break if you don't mind.
(Whereupon, a recess was taken from 11:06 a.m. to 11:15 a.m.)
BY MR. THOMAS:
Q. Doctor, what is environmental stress cracking?
A. Environmental stress cracking is the degradation of a polymer from imbibing, or the absorption of materials, in this case like

Page 87

cholesterol, cholesterol esters, fatty acids, into the interstitial space between the polymer chains which causes it to swell, creating stress, which eventually ruptures some of the polymer chains, causing degradation.
Q. Is it your opinion in this case that the mesh explants that you analyzed exhibit environmental stress cracking?
A. Sorry. Repeat the question, please?
Q. Is it your opinion in this case that the mesh explants that you analyzed show environmental stress cracking?
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
A. When I look at SEM photographs and see the cracking, I can't tell just from looking at the cracking whether it was oxidative damage or environmental stress cracking that caused that damage, or a combination of both.
DSC is one of the best techniques to suggest that, because we can measure the melt point, and we can measure the Delta H at melt which correlates to the amount of crystallinity. So as the Delta H of melting goes down, the

Page 88

amount of crystallinity goes down. Delta H of melt goes down, the percent crystallinity goes down, the percent amorphous goes up, which then that material, the amorphous material, is what is susceptible to environmental stress cracking.
BY MR. THOMAS:
Q. Doctor, do you have an opinion in this case as to whether the mesh explants that you analyzed show environmental stress cracking?
A. I think as one of the components I have an opinion, because we saw a drop in the Delta H at melt, of the explants.
Q. Is it your opinion that the drop in the Delta H in the DSC testing is proof of environmental stress cracking?
A. It's just like the lack of antioxidants. It's consistent with, it's not by itself proof of. But it's proof of the susceptibility of the polymer to environmental stress cracking.
Then I have to go back still, ultimately back to the SEMs, because the fact is not in question. It's occurring, we can see it. The question is why, and that way we have to -- now we have to look at a series of data to make

Page 89

our best judgment. I think in many cases the damage is caused by both.
Q. So just so I'm clear, your opinion that the mesh that you've analyzed in the explants has undergone environmental stress cracking is due to your visual observation on the SEM images and the DSC data, correct?
A. Right.
Q. Is there any other information that you determined from your report, or your work in this case, that you rely upon for your opinion that the explanted mesh underwent environmental stress cracking?
A. Any other data from my report, that was the question?
Q. Yes.
A. No.
Q. All right. Do you agree that pelvic organ prolapse is well-known for its high resistance to environmental stress cracking?
A. Yes. But the fact of the matter is the Delta H is going down, so something is causing that amorphous region to increase.
Q. And the Delta H you're talking about is the melting point as measured by the DSC

Page 90

measurements, correct?
A. The melting point goes down, and the Delta H at melt goes down. And again, there's variability from sample to sample. So some samples have more component of potential, I'll describe it as potential environmental stress cracking, and other samples from less potential. The same way I would describe the lack of antioxidant to be potential oxidation.
In all cases we are seeing the degradation through SEM of the polypropylene. That's just a fact. And we know it's polypropylene because the infrared spectrum is that of polypropylene, the flakes.
Q. What's crazing?
A. Small cracks.
Q. What does crazing have to do with environmental stress cracking?
A. Well, it's the start of the process. When you have a little bit of cholesterol ester you have just little cracks, little start, it's moving in, the process is beginning.
Q. Are you familiar with a concept known as crack initiation?
A. That's what crazing does, is initiates

Page 91

the forming of the larger cracks.
Q. So when you have smaller cracks and things get in there, then the cracks get bigger?
A. Basically.
Q. What's crack propagation?
A. Once a material starts to crack, it's like a rip in a garment, it's going to just -- once the rip starts, it's easier to continue it.
Q. Are you familiar with a concept known as fast crack propagation?
A. No, I'm not.
Q. Do you know the extent to which environmental stress cracking in polypropylene could be expected to be slow or fast, or there in small forms forever? Do you have any idea of the relative -- strike that. That's a terrible question.
Doctor, do you have any ideas about the expected progress of crack propagation in polymers?
MR. ANDERSON: Objection to form.
Go ahead.
A. It would depend on the environment again. Again, if some patients have more, there's more cholesterol esters that can get in,

Page 92

fatty acids and the like, then the process would be more rapid than they would if there weren't as much cholesterol, cholesterol esters in a given patient. That depends on the patient's disease state, for example, their weight.
BY MR. THOMAS:
Q. Do you have an opinion in this case about the expected rate of crack propagation in the mesh implanted in Carolyn Lewis?
A. No.
Q. Do you have an opinion about the expected mesh -- excuse me, crack propagation of the mesh implanted in Linda Batiste?
A. Well, the fact of the matter is I can see the cracks, I'm looking at them with SEM. That's all I can say.
Q. Very specific question.
Do you have an opinion about the expected time for the crack propagation in Linda Batiste?
A. No, I don't.
Q. Are you able to analyze the mesh explants and determine how long the mesh has been cracked?
A. No. Just the fact that it is.

Page 93

Q. Are you able to analyze the mesh explants that you've reviewed in this case and determine or measure the extent of the cracking?
A. Well, visually it's quite obvious that --
Q. I'm talking about quantitatively.
A. There is no way to do that short of looking at the pictures, that I'm aware of. I don't know anybody using a scale.
Q. Do you have an opinion in this case, first of all the Carolyn Lewis case, about the extent to which any degradation in her -- strike that.
Do you have an opinion in the Carolyn Lewis case about the extent to which any environmental stress cracking impacts the functionality of the polypropylene mesh for its intended purpose?
A. Let me look at the -- I have to look at the DSC data.
Q. This is very specific. This is Carolyn Lewis.
A. Correct.
(Witness reviewing document.)
A. Okay. What's the question, please,

Page 94

again?
BY MR. THOMAS:
Q. Do you have an opinion in the Carolyn Lewis case about the extent to which any environmental stress cracking impacts the functionality of the polypropylene mesh for its intended purpose?
A. I do not.
Q. Do you have an opinion in the Carolyn Lewis case about the extent to which any oxidation impacts the functionality of the polypropylene mesh for its intended purpose?
MR. ANDERSON: Objection as to form.
A. Of oxidation effects the --
BY MR. THOMAS:
Q. Correct.
A. Now I have to go through and look and see if --
(Witness reviewing document.)
A. Well, the infrared spectrum on Page 71 is a Carolyn Lewis sample. It has a carbonyl band, so the little band that's in front of the amide 1 is a sign of oxidation.
BY MR. THOMAS:
Q. That's not my question, Doctor. Let

Page 95

me ask it again. Very specific question.
Do you have an opinion in the Carolyn Lewis case about the extent to which any oxidation impacts the functionality of the polypropylene mesh for its intended purpose? Do you have a specific opinion in that regard?
A. My opinion would be it appears oxidized, so yeah, it would be degraded.
Q. Does it have any have oxidation -- do you have an opinion about whether the Carolyn Lewis mesh explant has oxidation that impacts the functionality of the polypropylene mesh for its intended purpose?
A. Any oxidation is bad. I see carbonyl is oxidation, so yes, my answer is yes, I have an opinion.
Q. What is the opinion?
A. It's damaged.
Q. How does the damage that you observed affect the ability of the polypropylene mesh to function in its intended purpose?
A. Well, something had to cause it to have it removed. I'm looking at the pictures, it's flaking, I'm looking at the oxidation, it's oxidized. I don't know how else to answer the

Page 96

question.
Q. Based upon your review of the mesh in this case and your analysis in this case, tell me how the oxidation of the mesh in Carolyn Lewis impacts the functionality of the polypropylene mesh for its intended purpose? How does it do it?
A. When you get ketones in the polymer, aldehydes in the polymer as reflected in these carbonyls, you -- that leads to ultimately to chain -- what we call chain beta scission, chain scission, which is degradation. And besides, it causes embrittlement in its own right. Very low levels of oxygen incorporated into polypropylene causes a material to become rigid which is classic of this.
Q. What is it about your work in this case that causes you to have the opinion that the oxidation of the mesh in Carolyn Lewis impacts the functionality of that mesh for its intended purpose?
A. Oxidation is bad. We see it.
Q. Okay. Are you able to measure the amount of oxidation that occurred in Carolyn Lewis quantitatively?

Page 97

A. No.
Q. Can you tell me anything more than oxidation is bad in support of your opinion that the work in this case shows that the mesh implanted in Ms. Lewis was not able to perform its intended function?
A. The antioxidants were missing. The material is not protected. I think we see -- we go over and look at EDX results, if I can find --
(Witness reviewing document.)
BY MR. THOMAS:
Q. You can look all you want to. Do you want to continue your answer? I don't think you answered my question, but you can do whatever you think you need to do.
MR. ANDERSON: He's trying to ask you what about the oxidation in Carolyn Lewis, in your opinion, affects the function of the device for its intended purpose.
A. All oxidation affects the function.
MR. ANDERSON: How is what he's asking you.
A. It makes it more rigid. It makes it more brittle eventually. It causes it to flake.

Page 98

BY MR. THOMAS:
Q. How much oxidation is required for the mesh to be more rigid?
A. I can't answer that question sitting here, but it's not very much from reading the literature. 1 percent increased oxygen would probably do it.
Q. How much oxidation is required to make the polypropylene more brittle?
A. It's a process. It's not a single point. So I felt this material in my fingers, I could feel the rigidity in it compared to the straight.
Q. Very simple question. How much oxidation is required, Doctor?
A. I don't know.
Q. How many oxidation is required to cause the polypropylene to flake?
A. Anywhere from none to a lot, because it depends if it was environmental stress cracking you wouldn't necessarily to have oxidation for environmental stress cracking, or it could be totally related to oxidation, or it could be a mix.
Q. Dr. Jordi, you report in Exhibit 1 and

Page 99

2 the observation of cracking perpendicular to the extrusion lines in the mesh?
A. Yes.
Q. And what are extrusion lines?
A. Well, you just can see them in the -- I think they're little -- probably caused by miniature, if you want to call it, defects in the dye.
Page 25 is a typical example. You can see the lines moving along the line of extrusion.
Q. Extrusion is a process by which the fibers are formed?
A. I believe so, yes.
Q. Are you familiar with the extrusion process?
A. Not a lot.
Q. Okay.
A. I'm more an analyst.
Q. Are you comfortable with calling the extrusion lines the grain of the fiber?
A. Sure.
Q. Okay. And when we talk about the perpendicular cracks, we're talking about the cracking that you observed being perpendicular

Page 100

to the extrusion lines, or the grain of the mesh?
A. Correct.
Q. Have you analyzed the extent to which perpendicular cracking is consistent with the chemical structure of the mesh?
A. Repeat the question, please?
Q. Have you analyzed the extent to which perpendicular cracking is consistent with the chemical structure of the mesh?
MR. ANDERSON: Objection as to form. Go ahead.
A. When you put a material through the dye, you'll be aligning the polymer chains along the line of the fiber so that only -- you basically only have London-London forces of the CH2 groups and CH3 groups in the polymer backbone holding the polymer together, so it will be more easily cracked -- if you bend it it's going to tend to crack vertically to the direction of the fiber.
BY MR. THOMAS:
Q. Okay. Is that something you studied before I asked you the question, or you just answered that question based upon your

Page 101

knowledge?
A. Based on my knowledge.
Q. Okay. Did you study, as a part of your analysis of this case, the extent to which cracking would be expected along the grain or extrusion lines of the mesh as compared to the perpendicular angle that's called out in your report?
MR. ANDERSON: Objection as to form.
A. Again, I have to have it repeated. Sorry.
BY MR. THOMAS:
Q. Did you study, as a part of your analysis of this case, the extent to which cracking would be expected along the grain or extrusion lines of the mesh as compared to the perpendicular angle that's called out in your report?
A. Well, what's called out in my report was what we observed.
Did I study differences? It's not a perfect thing. You can see cracks in other directions, too, sometimes, it's just a majority seems to be in the vertical.
Q. Okay.

Page 102

A. And furthermore, you can see these -- the grain, as you call it, is running right through these cracks, so that's further information to suggest that these -- this cracked region is not biofilm, it's polypropylene, because it's got the same grain in it the original polypropylene did in the cracked pieces. If it was biofilm, those marks should go away. They don't, they're there.
Q. Have you analyzed the issue of environmental stress cracking to determine whether environmental stress cracks would run with the extrusion lines or the grain as opposed to the perpendicular manner in which you call out in your report?
A. Have I analyzed that? No.
Q. The crazing that you've talked about are the areas in the mesh that are furthest away from the crystals in the mesh, is that fair, in the amorphous regions?
A. In the amorphous regions, yes.
Q. And the crazing that you've talked about is the small cracks that form in this amorphous region, correct?
A. Yes.

Page 103

Q. Knowing what you do about polypropylene, and the chemical structure of it, and the crazing that you've just described, wouldn't it be more likely that any environmental stress cracking would occur with the grain or along the extrusion lines of that mesh as opposed to perpendicular to the mesh?
A. The -- if you -- well, first of all, the fact of the matter is it's vertical to it. I mean that's just a fact for the vast majority of them.
Q. I'm asking you based upon your knowledge as a biochemist, your knowledge of polypropylene, and your knowledge of the chemical structure, and the way that you've described the environmental stress cracking as we've been through it, isn't it more logical to conclude that environmental stress cracking would occur along the grain or the extrusion lines as opposed to perpendicular to those lines?
A. If you wanted -- if you picture long chains going this way of polymer, and then you bent it this way, then it's going to tend to crack here because those chains are going to

Page 104

come apart in the amorphous region. They don't have as much force holding them together. You have to literally rupture chemical bonds.
I don't see what you're saying, I'm sorry.
Q. So is it your testimony that to have the oxidation or environmental stress cracking necessary to cause the cracking on Page 40 in Figure 44 of your report, Exhibit 1, requires a rupture of the chemical bond?
A. I would think that would be true on the surface, yes.
Q. Okay.
A. Has to be.
Q. And every place that you see this cracking in the scanning electron microscopy, the images that you've talked about, in order to get the cracking that you describe shown in the SEM images requires a breaking of the chemical bond; fair?
A. I think so.
Q. Let's go to your report, Exhibit Number 1. Let's go to the PYMS data.
MR. ANDERSON: Page 80 you're showing?
MR. THOMAS: Page 80.

Page 105

A. Okay.
BY MR. THOMAS:
Q. Tell me what the PYMS technique is.
A. Stands for pyrolysis mass spectroscopy. The sample is heated, and until it fractures the bonds in the polymer releasing everything, small molecules and so on, and then those fragments are put through a GC column, then they're monitored by a mass spectrometer.
We tend to do a two step method as well where we heat the sample to 300C, which tends not to fragment the polymer, and that releases additives so we can see additives without being overwhelmed by polymer fragments.
One of the disadvantages of a PYMS by itself is that when you burn the polymer, in this case polypropylene, you get a massive amount of polypropylene fragment ions which tends to overwhelm the ability of a detector to sense sometimes certain ions, like the antioxidants, like Santonox, at least at the levels that we want to detect it at.
Q. As I understand your report and your earlier discussion, you used the PYMS analytical technique to determine the extent to which

Page 106

additives in the Ethicon polypropylene mesh are present?
A. That's right. I mean that's one of two. We use the LCMS as well.
Q. Start with this one. Tell me how you do that.
A. How you determine --
Q. Right.
A. You -- well, you would first, if you're looking for Santonox R, you would shoot a standard of Santonox R, and then you would look for the ions that you get. Santonox R gives ions at 358 and 343 atomic mass units, so you would plot those ions and look at them as shown on figure -- well, the ions aren't shown in Figure 82, but the chromatogram is.
Q. Let's back up a minute.
When you're doing this test, do you test both the explants and the controls?
A. Absolutely.
Q. And why do you do that?
A. Because you want to look for differences again. First of all, we want to be sure that the pristine has it in it, and it did. And then we want to see whether or not the

Page 107

explants have it in it.
Q. Okay. Did you test the formalin controls as a part of the PYMS test?
(Witness reviewing document.)
A. It's not shown here. I'm going to have to go in the original data. A lot of the stuff that was in the original data is not in this part.
MR. ANDERSON: Go to the original data.
MR. THOMAS: Is that all data that's been produced to us already?
A. It's all here, except you've got it on dual sided. It's all here. So I have twice as much paper.
BY MR. THOMAS:
Q. While you look for that, I'm going to go to the restroom.
(Pause.)
A. Repeat the question. I'm sorry. I think I've got pretty close.
BY MR. THOMAS:
Q. Did you test the formalin control as a part of the PYMS test?
A. I didn't see it, no.

Page 108

Q. Why not?
A. We didn't think it would have any effect on the results.
Q. Why?
A. It's not an extracting solvent. It's going to dissolve polypropylene, so it's not going to have any rapid effect on an extraction.
Q. Why do you say that?
A. Well, the polypropylene is solid. It doesn't leach out additives quickly unless you put it in proper solvent extraction methods. Or this case it was simply there, we didn't do an extraction method, that's the LCMS, we just simply put it in the sample holder and shoot it.
Q. Have you analyzed the extent to which formaldehyde is an oxidant?
A. No.
Q. And to the extent formaldehyde is an oxidant, you'd expect formalin to be an oxidant, wouldn't you?
A. Right.
Q. To the extent that formalin is an oxidant, it would be appropriate to test the polypropylene pristine samples in formalin as a part of your PYMS analysis, wouldn't it?

Page 109

A. It certainly could be done, but we didn't do it.
Q. Because if you found that the antioxidants were substantially reduced in the formalin control sample, that would impact your opinions, wouldn't it?
A. Yes.
Q. Why?
A. Well, then we would imply that the formalin extracted the polypropylene additives out.
Q. Have you analyzed at all in connection with your work in this case the extent to which formalin will extract the antioxidants from the polypropylene mesh used in the TVT device?
A. We didn't do any work with formalin, so no.
Q. So what your findings in the PYMS section of the report show is only the pristine mesh compared to the explanted mesh treated in formalin?
A. That's correct.
Q. Now, the next step you take in the antioxidant analysis is your LCMS work, correct?
A. Correct.

Page 110

Q. That's on Page 84 of your report.
A. Got it.
Q. And in this work, you did testing on the control samples, didn't you?
A. Yes.
Q. And you did test work on the formalin control samples, didn't you?
A. Yes.
Q. Turn to Page 96, please, of your report. Table 19.
A. 19 starts on Page 95, just so you know.
Q. Thank you. Take your time and look at both of them if you want to, both pages.
A. Okay.
Q. Let's just talk about it.
Page 95 begins at Table 19, and it's called "Santonox R Relative Quantification," and on the left you show sample, on the right you show peak area.
What are you trying to show in this table?
A. The relative amounts of Santonox R in the various fibers.
Q. And Santonox R is one of the

Page 111

antioxidants in the mesh?
A. That's correct.
Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh?
A. Yes.
Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct?
A. Making it, yeah, more susceptible to oxidation.
Q. All right. So on the left you have the numbers of your samples, correct?
A. Yes.
Q. And on the right you have the peak area of Santonox R. What does the peak area mean?
A. It's just we're plotting -- you can see the photograph here of the peaks for Santonox R right above it, retention time.
Q. Okay. So what does the chart on Page 95 represent above this table, the LCMS extracted ion chromatograms, and you have all the numbers of the samples, what does that mean?

Page 112

A. A lot of -- that's overlay of peaks of Santonox R for -- where Santonox R loops at 11.6 minutes about.
And extracted ion simply means we know we have the 357 ion that shows up, so we tune the instrument to see, or to record only the 357 ion, which is specific to Santonox R, ignoring all the other impurities, anything else that might also be co-eluting. So it makes the method specific.
Q. So how does the LCMS work?
A. The liquid is put in from a column into the detector and made into a mist, and a voltage is applied, and you get ions. The ions are put through quadripoles, which bends them. Then it goes through a big tube called a time of flight. When it starts going up the tube, a clock starts, hits the top, starts coming down, and when it reaches the detector at the bottom, it hits the other clock, measures literally the time between the start and the impact on the detector. And then that time is related to the mass. It gives you a very accurate mass, which is the point of CUTO, giving you very accurate mass.

Page 113

Q. What does peak area mean that's reported in Table 19?
A. Just integrate the area under the curve that's observed.
Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct?
A. That's correct.
Q. So, for example, in 13674, the peak area is 315,246?
A. Correct.
Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample?
A. That's pristine control. There's some variability there.
Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct?
A. That's correct.
Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand 324,899, correct?

Page 114

MR. ANDERSON: Objection. Million.
MR. THOMAS: Thank you.
A. Millions, yes. But you're right.
BY MR. THOMAS:
Q. If you look at the formalin treated control samples on Page 96 at Table 19, the formalin treated control samples have less Santonox R than the regular control samples, don't they?
A. They do.
Q. Did you make any analysis to determine why?
A. I would assume that that -- you have to assume by the data that that means that the -- because it was the same 3405405 was analyzed before and after the formalin treatment, so formalin treatment extracted some of the antioxidant.
Q. Let's look at that, because the formalin treated control sample is 3405405, and it says 2,216,989.
A. Right.
Q. If you go up to the control sample with the same lot number, that means it's the same material, just with no formalin, correct?

Page 115

A. That's right.
Q. And the peak area there is 4,012,675, correct?
A. Yes.
Q. Can't you conclude from that that the formalin is extracting the Santonox R from this mesh sample?
A. You can. Not completely, but it is.
Q. Okay. Is there any other explanation for what's going on there?
A. I don't think so.
Q. Now, if you look at the other formalin control sample, lot number 3422128, it shows a peak area of 1,019,604. And if you compare that to the same control sample without formalin, the number is 4,550,748, correct?
A. Yes, you're right.
Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct?
A. Correct.
Q. And you have to conclude that the reason why there's less in the formalin treated sample is because the formalin extracted out that Santonox R, correct?

Page 116

A. That's the only explanation I can think of.
Q. But you didn't study the extent to which formalin impacts the antioxidants in the mesh as a part of your analysis in this case, correct?
MR. ANDERSON: Objection as to form. Go ahead.
A. No.
BY MR. THOMAS:
Q. It's correct that you did not?
A. I did not.
Q. Thank you.
Now, if you look at the same table, Table 19, you look at lot 3422128.
A. Where are we now?
Q. Under "Control Samples," same table, Table 19 on Page 96.
A. Okay.
Q. You see that there's a control sample which is lot number 3422128. Do you see that? And a value of 4,550,748. Do you see that?
A. I see it.
Q. And then there is another -- a duplicate of that same control sample also

Page 117

tested. Do you see that?
A. Yes.
Q. And for that duplicate, that's the same piece of mesh, isn't it?
A. It's a different sample, but it would be the same piece of mesh, yes.
Q. And that's a duplicate of the same test with the 4,550,748 test, right?
A. Right.
Q. And the value that you get for the duplicate sample is 5,418,177, correct?
A. Correct.
Q. Do you have any explanation for the difference in peak areas between these two, what should be duplicate samples?
A. It should be duplicate samples, but it's a different -- it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's regions of higher and lower concentration.
Q. Do you know?
A. No. I'd have to run a series of tests. That's what it's suggestive of.
Q. Does the fact that the control sample

Page 118

and the duplicate control sample of the pristine mesh tested almost a million DAs apart, does that cause you any concern at all?
A. Well, if it's different it's different. I can't control that.
Q. Okay. Does the fact that the control sample lot 3422128, the duplicate, shows a peak area of 5,418,177, and the formalin treated control sample for the same piece of mesh is less than 20 percent of that value, does that have any concern -- cause you any concern about the opinions you have in the case?
A. Where are we here? Sorry.
Q. Okay. We're at Table 19, Page 96. You have --
A. Duplicate.
Q. You have your duplicate lot for 3422128, the value is 5,418,177. And the same piece of mesh treated with formalin is less than 20 percent the concentration of Santonox R as you found in your pristine sample.
A. Yes. It looks like formalin is extracting it, as we said before.
Q. Why didn't you note that in your report?

Page 119

MR. ANDERSON: Objection.
A. I did. It's in the table.
BY MR. THOMAS:
Q. Why didn't you discuss it in your report?
A. Well, there's normally experimental error, I can't -- it's possible that this million is there because -- instead of 2 million because, again, we hit a region of lower concentration of the Santonox R, that could be part of the reason. Because we see spread in the other control values as well.
Q. Doctor, isn't the best evidence based upon the work that you did in this case that the formalin is extracting the antioxidants from the mesh?
MR. ANDERSON: Objection as to form. Go ahead.
A. Well, it is extracting some of the Santonox R. However, even at the lowest level for the majority of these samples, like 13416, 13418, 13421, there's 67,000 counts to 100,000 counts, which is 10 to 15 times less than even the lowest for formalin control.
BY MR. THOMAS:

Page 120

Q. You had samples in the formalin control for how long? 48 hours at 60 degrees centigrade?
A. Yes.
Q. Did you make any effort to correlate the aging by that amount to the samples that are contained in Table 19 to determine whether they're equivalent?
A. No.
Q. It would be appropriate in any scientific analysis to make sure that when you're comparing formalin exposure, you want them to be equal to make sure that they reflect accurate values?
A. Well, the only way to do that, it would be rather impossible in this case, it would have had to have been implanted in tissue, and had to have been implanted and stored in the formaldehyde for -- you know, like we'd have to take controls. I don't know how we'd put controls in tissue. There's all kinds of possible requirements to do that technically.
Q. Is it fair to conclude based on the data in your report, at least with respect to lot number 3422128, the duplicate sample, and

Page 121

the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R?
A. Given the spread on the data, it's certainly -- it is suggestive of that. But again, it could be 40 percent or 60 percent or 50 percent because it could be a different region of the fiber itself. We have normal spread if we run a duplicate like above.
Q. Let's go above. It's -- even if you go to the duplicate above --
A. That's what -- that's not 80 percent difference from the duplicate, it's 20 percent.
Q. It's almost 50 percent, isn't it?
A. No. 4,550,000 versus 5,400,000.
Q. But those are not formalin treated?
A. No, but that shows the natural variability of the mesh.
Q. But you only -- okay.
The only data that you have on your tests under the LCMS of these explanted meshes are contained in this report, correct?
A. That's correct.
Q. And these are the data upon which you rely for your opinions in this case?

Page 122

A. That's correct.
Q. And you could have tested other regions in the mesh to determine the extent to which the antioxidants varied across the mesh, correct?
A. Theoretically. We did a huge amount of work to begin with, so it's all a relative -- what you're capable of doing in the required time and all the rest of it, so it's just a judgment call.
Q. The reason why you did testing was to have the data points upon which you could predicate your opinions?
A. That's right.
Q. And these are the only data points that you have upon which to predicate your opinions?
A. That's right.
MR. ANDERSON: Well, objection to form.
A. Not the only, but it's one of.
BY MR. THOMAS:
Q. For this issue, for the LCMS data?
A. For Santonox R for the LCMS data, for the lauryl thiodipropionate, for example.

Page 123

Q. As a scientist who works in biochemistry and uses this type equipment, does the variability in the data in Table 19 on Page 96 suggest to you the need to do additional testing to confirm the extent to which formalin was involved in the extraction of the antioxidants?
A. That would be a good idea, sure.
Q. Because the data as expressed here is not reliable, is it?
A. Well, that's a relative term. I think we certainly got nowhere near the levels seen in the explants.
Q. Is it still your opinion that to a reasonable degree of scientific certainty that formalin has no impact on the Santonox R in the mesh as implanted in a person?
A. As implanted in a person, I don't --
Q. Bad question.
Is it still your opinion to a reasonable degree of scientific certainty that the formalin had no impact on the measurement of antioxidants in the meshes analyzed by you, the explants?
MR. ANDERSON: Objection.

Page 124

A. It did not remove at all. It didn't remove it to the same levels as seen in the explants.
BY MR. THOMAS:
Q. But it's true to a reasonable degree of scientific certainty as reflected by your data that the formalin removed more than 80 percent of the antioxidants as expressed in that data?
MR. ANDERSON: Objection.
A. I have to look at the numbers.
(Witness reviewing document.)
A. The samples -- that's true. And in the samples as received, we had like 1, 2 or 3 percent left, not 80 percent. We only had -- so it had 97, 98, 99 percent removed in the explants we received. Still greater.
BY MR. THOMAS:
Q. But you don't know how long those explants were exposed to formalin, do you?
A. No, I do not.
Q. And the length of time those explants may have been exposed to formalin would impact the extent to which the formalin extracted the antioxidants, correct?

Page 125

A. Presumably.
Q. Well, absent any testing showing you otherwise, that would be the logical conclusion from this data, wouldn't it?
A. Yes.
MR. THOMAS: Let's eat.
(Whereupon, a luncheon recess was taken at 12:15 p.m.)

Page 126

AFTERNOON SESSION
1:12 O'CLOCK P.M.

BY MR. THOMAS:
Q. Let's spend a little time with your report, Dr. Jordi.
A. Okay.
Q. The report in the Lewis case. Let's go back to Page 16 again.
Table 2 on Page 16, it begins on Table -- on Page 15, I guess, to be fair.
A. Yes.
Q. Table 2 represents what?
A. Table 2 represents a grid of the tests that were run.
Q. There is a number of sample identification numbers beginning with 13400 that run to 13421. I assume you did all of those tests at once, or about the same time?
A. About the same time. We received the Lewis case a little bit later, so it was run a little bit later.
Q. Is it your practice to number the testing that you do in your labs sequentially?
A. Yes.

Page 127

Q. Is there any significance to the numbers, other than the time that you do it?
A. I don't believe so. It's just the standard SOP numbering.
Q. Okay. When did you do the testing for 13400 to 13421, over what period of time. I don't think you'll find it in your report. I've got the bills here if that helps.
MR. ANDERSON: Lab notebooks would help, too.
A. Lab notebooks would probably be better.
BY MR. THOMAS:
Q. Okay.
(Witness reviewing documents.)
A. Looks like about the start was 9/9.
MR. ANDERSON: Look at your lab notebooks instead of saying "about."
THE WITNESS: I did look at the lab notebook there.
These were all these samples that are in that grid, so 9/11, 9/13.
BY MR. THOMAS:
Q. Just from the bills I looked at, it appears that the work that has been done in this

Page 128

case has been done since -- the testing work itself has been done since September. Does that seem about right?
A. Yes.
Q. Okay. In Table 2 on Page 15 there's identification of the sample, weight, fibers. Is that molecular -- what is the weight for that? What does that mean?
A. That was the amount of fibers that were able to be extracted. So when you look at the picture of the -- on Page 16 at the bottom left, those fibers after they were removed from tissue were weighed.
Q. Okay. Is there any weight of a tissue that you have?
A. No. We had no plans for analysis of the tissue.
Q. Did you retain the mesh fibers that are in Figure 2?
A. Well, we would have if there were any to maintain. There may be tidbits of a couple of them. But with all the testing that was done, we were extremely sample constrained.
Q. How about the tissue samples, did you retain any of the tissue samples?

Page 129

A. No. We had no further use for the tissue.
Q. Under the 13674, you understand that to be the Carolyn Lewis sample?
A. Yes, I do.
Q. There's no weight taken there. Do you know why?
A. It was an oversight. It's 7.62 milligrams. It's in the book.
Q. Okay. So it's in your lab notebook, but never made it to your report?
A. That was a glitch. It should have made it to the report. It didn't make it to the report.
Q. What's the significance of --
A. It's 7.62 if you want to write it in so you've got the exact number.
Q. What is the significance of that number to your analysis?
A. The milligrams?
Q. Yes, the weight of the fibers that you receive.
A. It's just a fact of what we got.
Q. That's what I figured.
As I look at the sample, explant

Page 130

sample analysis chart, it lists the tests done on each sample, correct?
A. Correct.
Q. You didn't do all of the tests on all the samples?
A. Correct.
Q. Why?
A. Some cases there just wasn't enough sample to do them all. And other cases we -- like we ran SEM and optical microscopy on all the samples. SEM-EDX, once we've seen increased oxygen six times, we didn't feel it was necessary to run them all. It's already a huge report. The volume of work was so great that we made choices when we had acquired what we considered a significant level of work. Once I prove something six times, I don't need to prove it seven, eight, nine, ten times. Part of it was lack of sample, part of it was we'd run enough to be consistent to show the point of the various analyses.
Q. Did the expense of the test have anything to do with it, the expense of each of the tests?
A. I'm sure that wasn't the overriding --

Page 131

that wasn't the overriding thing.
Q. Did you determine which fibers to test with which test, or were you directed in that regard?
A. No. We discussed that, and we just made a choice of statistical significance.
Q. Who made that decision?
A. Well, my son Mark and I.
Q. Okay. What considerations did you have in determining, for example, to do all of the OM and SEMs, but only some of the SEM-EDX?
MR. ANDERSON: Objection. Asked and answered.
Go ahead.
A. We just didn't feel it was -- we had showed the point, and we just thought we had done enough work. And we had a huge work product to begin with.
BY MR. THOMAS:
Q. Okay. Is there a reason -- strike that.
Let's go to Page 19. Page 19 in the middle of the page, it reads this. "It is my opinion to a reasonable degree of scientific certainty based upon my experience and my

Page 132

background in polymer science, this level of degradation will have a strong impact on fiber mechanical properties, including stiffness, elasticity, and resistance to break."
What level of degradation are you describing in that sentence?
A. We're describing the very obvious cracking seen in the SEM photographs.
Q. Okay. So the level that you're describing there relates solely to what you observed in the SEM photographs, images?
A. At this point, yes.
Q. All right. "Will have a strong impact on fiber mechanical properties." What does that term mean to you? How much is strong?
A. Well, we weren't able to run physical testing that we normally would run, because we didn't have enough material, but we could feel, one way is to feel it. The material explanted material had a much more rigid feeling to it, I guess the best word is rigid, rigid feeling to it than the controls.
Q. Okay.
A. It was very obvious.
Q. Is that the only information that you

Page 133

have that the level of degradation that you observed would have a strong impact on fiber mechanical properties?
A. No. If I looked at the actual flaking and the cracking and so on and so forth, that's got to have a massive effect. It's a large -- it covers the entire region of some of the fibers.
Q. Okay. You call it strong, you said massive. What does that mean?
A. Well, the best way I can show it is with a picture.
Q. Okay.
A. Do you want to see one?
Q. You've showed them to me, and I've seen them.
In terms of quantifying, placing a number on the impact on the mechanical properties, you're not able to do that, is that fair?
A. I think you could certainly say it was great -- very greatly cracked or moderately cracked, something like that in general. Putting a number score on it would be difficult, yes. But it certainly is not hard to look at a

Page 134

sample that's grossly cracked and see that it's grossly cracked.
Q. You say that it's "going to have a strong impact on fiber mechanical properties, including stiffness."
What impact will this degradation have on stiffness?
A. Cracking, the cracking to me is indicative of some -- is a form of degradation, at least it's a result of the chemical degradation, results in a physical splintering that we see. So that when it's largely cracked, that also implies that the material underneath it is probably cracking, too. And I prove that by showing the SEM-EDX and showing the increased oxygen levels in the level underneath the cracks, that's the next layer that will crack.
Q. Thank you, Doctor.
My question is; what level of -- strike that.
What amount of stiffness is impacted by the level of degradation that you observed in the SEM images? What's the -- how can you quantify the level of stiffness?
A. I can just feel it. I'm sorry, I

Page 135

can't give you a number.
Q. And just so it's clear, the only thing that you have to go on about the stiffness is holding the explant in your hands?
A. In the gloved hands.
Q. Okay.
A. And -- yes.
Q. Comparing it to --
A. To the control.
Q. -- the control.
Did you compare that to the formalin control, or just the control?
A. I think we felt them all.
Q. I didn't see any reference in your report to the formalin control.
Do you have a -- is it your practice when you test the formalin controls to reference that in your report?
A. Reference what in the report?
Q. The fact that you did it.
If you go on Page 17, it's where you talk about handling it. Page 17 says "It was noted during sample preparation that a readily apparent difference in fiber stiffness existed between the control samples and the explanted

Page 136

fiber mesh."
There's nothing in there that I saw that suggested that you compared the formalin control samples. Do you recall testing the formalin control samples in the same way that you tested the control samples and the explants?
A. It's not specifically mentioned, but we felt them.
Q. Okay. And it's your recollection and testimony that the explanted samples felt stiffer than the control samples?
A. Most definitely.
Q. And did you arrive at any conclusions about what caused that stiffness?
A. At the time it was done, we hadn't done the other testing, so I had no reason or cause. After all the work that's done and reported here in this report, the infrared showed oxidation, the SEM-EDX shows oxidation, the lack of antioxidants would suggest susceptibility to oxidation, and so on.
Q. Okay. The sentence also references elasticity. Was the elasticity also something that you observed in the handling of the mesh?
A. Right. If you bent the original --

Page 137

the pristine mesh it would come -- pop right back to shape. And the other, you had to apply more force to get it bent, and it would come back and sometimes would stay partially bent, or sometimes would crack.
Q. Is it the handling of the mesh the only basis for your opinion that the explanted mesh was less elastic than the control?
A. As a comment here, yes, because that's a point where we were running SEM.
Q. And likewise, with the resistance to break, did you observe that in your handling as well?
A. That's right.
Q. And is it fair to understand that it's your handling of the explanted mesh as compared to the control mesh that's the basis for your opinion that the explanted mesh had less resistance to break than the control mesh?
A. Yes. The control mesh never broke.
Q. Did you ever investigate any alternative potential causes to more stiffness, less elasticity, or more resistance to break?
A. No. We were going after chemical analysis of the polypropylene and the

Page 138

differences, if any.
Q. Did you ever consider any other chemical contributions to increased stiffness -- strike that.
Did you ever consider whether formalin could contribute to increased stiffness, less elasticity, or less resistance to break?
A. We felt it. The same, it felt the same.
Q. Did you consider that at the time?
A. If it had been different it would have been reported. The fact that it was a formalin treated control would be part of the control package.
Q. Well, the formalin treated control observations weren't even called out in your report, right?
A. That's right, they weren't.
Q. Okay. Did you ever consider the extent to which formalin and a chemical reaction with the proteins on the mesh could lead to an increased stiffness, a reduced elasticity, or a reduced resistance to break?
A. No.
Q. Down in the middle of that paragraph

Page 139

you say "Sharp or protruding surfaces could result."
Do you have an opinion to a reasonable degree of scientific certainty that any sharp or protruding surfaces resulted from any of these pieces of mesh?
A. Where are we reading here?
Q. Right in the middle of that paragraph.
MR. ANDERSON: Page 19.
A. Oh, 17. All right. Which paragraph?
MR. ANDERSON: You're on 18. He wanted 19. He's going to keep going through this paragraph, so here's where he is right now.
A. "Sharp protruding..."
(Witness reviewing document.)
A. Okay. Question again, please?
BY MR. THOMAS:
Q. Do you have an opinion to a reasonable degree of scientific certainty that any sharp or protruding surfaces resulted on any of the mesh explants that you reviewed in vivo?
MR. ANDERSON: Objection to form.
A. We saw the sharp edges in the SEM photos.
BY MR. THOMAS:

Page 140

Q. How do you know that's the way it was inside the body?
A. Well, it was in the tissue when it came, and we didn't take it out of the tissue when we sent it -- when we ran the SEM, so we didn't do anything different than it was in the body environmentally. We did that on purpose.
Q. You didn't do anything differently, but the doctors did something differently when they removed the mesh, didn't they?
A. Well, they took it out of the body, yes.
Q. What else did they do?
A. Put it in formalin.
Q. Okay. Do you know what impact the formalin has on the proteins and other -- strike that.
Do you have any knowledge or information about what formalin does to the materials in the body that surround the mesh?
MR. ANDERSON: Objection to form.
A. It will react with the tissue, but it will not react -- we ran controls in formalin here, and we showed it didn't change the SEM.
BY MR. THOMAS:

Page 141

Q. But the ones you ran in formalin didn't have any tissue on them.
MR. ANDERSON: Wait a minute, Dave, in fairness let him finish his answer.
MR. THOMAS: You're right.
A. We ran formalin treated controls here to see if it would do anything obvious to the pristine. It did not.
BY MR. THOMAS:
Q. But the formalin controls that you ran didn't have any tissue on them.
A. That's correct. So what?
Q. And my question is whether you know whether formalin will react with the tissue on the mesh so as to impact the appearance in the SEM images. Do you know that?
A. Absolutely not. It will react with the tissue, absolutely. It's irrelevant. It's not going to react with the mesh. It will react -- not react with the mesh in the tissue, it will react with the tissue which we removed, so it's no longer there when we did the testing.
Q. Is it your testimony there was no --
A. There was tissue on when the SEMs were run. We didn't want that removed because didn't

Page 142

want to in any way disturb the mesh in any way that we could possibly avoid, so we tried our very best not to cause anything, any changes. So we ran the SEMs in the tissue, which we could do.

Q. What is your area of expertise that allows you to give the opinion that "Prolene mesh in the TVT products degrades, cracks, and releases polypropylene particulates into the surrounding tissue after implantation, causing an increased inflammatory response"? Are you trained to give that opinion?

A. I certainly am. I'm a polymer chemist, a biochemist, and we actually saw the shards, we saw how easily the shards came off, and then we actually took an infrared of it to show that they were polypropylene. So we actually did it and we saw it.

Q. That's not -- that's a good answer. I should have asked a better question.

What's your training, education, and experience that allows you to give the opinion that those pieces that you claim break off caused an increased inflammatory response?

A. What's my basis?

Page 143

Q. Yes. What's your training?

A. I'm a biochemist.

Q. As a part -- have you analyzed the effect of polymer degradation in humans prior to this litigation?

A. I worked on bio-implantable polymers when I was in the Army at Walter Reed Army Medical Center, polylactic acid, polyglycolic acid copolymers.

Q. Was your work there --

MR. ANDERSON: He's not finished. Go ahead.

A. We were replacing parts of jaws in animals with a goal of being able to replace a blown off jaw on a soldier, put a piece of implantable material in the jaw, and then we wanted the tissue to grow into it, so we put things in the PLA-PG polymer so tissue would tend to grow in, and ultimately the jaw would be replaced with new jaw, and it worked fairly well.

BY MR. THOMAS:

Q. Was it your job to determine the extent to which the implant would be accepted by existing tissue?

Page 144

A. That was well understood in that we had very little response. Because in that case, unlike this case, we had a polymer in polylactic and polyglycolic acid which degraded to lactic acid and glycolic acid, both of which are normal body chemicals that don't cause a tissue response of any consequence.

Q. Was it your job to determine the extent to which the jaw implant would integrate into the tissue?

A. To observe it.

Q. Was it your job to determine the adequacy of the design of the jaw implant to be accepted by the tissue?

A. Well, we worked as a team. There was a number of us.

Q. But there were other people whose primarily responsibility was to determine the extent to which the implant was compatible with existing tissue, wasn't it?

A. That work had been done prior, it had been shown to be compatible.

Q. But that was not your job?

A. No.

Q. Somebody else did that work? Another

Page 145

expertise was required to make that finding, correct?

A. Right.

Q. And so --

A. But it's not unreasonable to observe polypropylene shards coming off, which are little knives. They're going to cut the tissue when they come off in it. You can see it under microscope, and that's going to cause bleeding and an inflammatory response.

Q. How big are these shards you're talking about?

A. Well, let's go look at a picture. We've got a scale on it. They vary.

Q. How big is that one? What page are you on?

A. 69.

Q. How big is it?

MR. ANDERSON: Which piece? There's pieces all over the place.

MR. THOMAS: The piece he has highlighted right there.

MR. ANDERSON: Okay.

A. Well, the mesh itself is, what, 70, 80 microns, so it's got to be -- this is a good

Page 146

size piece, so it's probably 20 microns, 10 microns, 20 microns, depends on the piece.
BY MR. THOMAS:
Q. And it's your opinion that that cuts tissue?
A. Absolutely. If it's got sharp edges like this and you're moving around and exercising, it's got to drive it into whatever --
Q. What have you done to study the extent to which a shard as depicted on the Page 69 is going to have any impact at all in terms of inflammatory response in a human?
A. I leave that to the doctors, the surgeons, and so on, and the doctors. I'm not a -- I'm a biochemist and a polymer chemist.
Q. Right. So the extent to which any of these edges that you've described, cracks that you've described, or platelets or shards that you've described are going to have any health impact on any patient is for somebody else to comment on, is that fair?
A. The doctors have to do that, yes.
Q. Thank you.
Let's go to Page 42 of your report,

Page 147

please.
A. Got it.
Q. I'm interested in the figure that's on the lower half of the page. I guess it's Figure 48.
Based on your work in this case, what does Figure 48 show?
A. It shows a large -- this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue.
Q. Okay. Which parts -- I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing.
Is the area surrounding the interior portion -- that's not going to make any sense at all on the record, I understand that. Are we talking about the same thing? Is that the tissue that's surrounding it?
A. Yes. This would be the polypropylene in here (indicating).
Q. Let me give you a red pen. Why don't

Page 148

you draw a circle around what you've described as the polypropylene.
MR. ANDERSON: On his copy? Do you want to put it on -- let's put it on the record copy.
MR. THOMAS: That's what I thought he was looking at. I'm sorry.
A. It would be the same page.
BY MR. THOMAS:
Q. So we're on Page 42 of Exhibit 1.
A. Yes.
MR. ANDERSON: You're going to write on this.
BY MR. THOMAS:
Q. So why don't you draw a circle around, if you don't mind, those areas --
A. Circle?
MR. ANDERSON: Listen to him.
BY MR. THOMAS:
Q. Outline the area that you believe is polypropylene.
A. (Witness complies).
I'm having a hard time writing exactly, but you give my drift.
BY MR. THOMAS:

Page 149

Q. Doesn't have to be exact.
A. Looks like a crack there.
Q. Okay.
A. Something on that order.
Q. And so thank you for doing that.
You've drawn in red the area inside of which is the polypropylene. Does the area outside of that represent tissue or protein?
A. I believe so.
Q. Okay.
A. It doesn't match -- you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more -- tissue is more nebulous.
Q. What is it about the polypropylene structure that causes it to crack in the manner you just described?
MR. ANDERSON: Objection to form.
Go ahead.
A. It's developed brittleness from lack of antioxidants and oxidation and/or stress cracking. The two work together in any given sample.
BY MR. THOMAS:
Q. Will degradation alter the melting

Page 150

point of polypropylene?
A. Yes.
Q. Will degradation always alter the melting point of polypropylene?
A. I think it depends on the severity of the oxidation, the degradation.
Q. How much degradation or oxidation is required to alter the melting point of polypropylene?
A. Well, a lot of things affect the melting point of polypropylene. I'll show you. This is again from one of the books in my -- Turi, on thermal methods. Here's a chart, it details polypropylene, and I've got melt points all the way from 106 to 114 degrees to 176 degrees, depending on the percent crystallinity. Percent crystallinity affects the melt point.
Q. Did you determine the melt point of the mesh that you analyzed in this project?
A. Yes.
Q. What did you determine the melt point to be, do you remember?
A. I'd have to go to the table. There were different values.

Page 151

Q. We'll get to that.
You use a reference point in your report of 175.
A. That's for a typically crystalline polypropylene material.
Q. The actual melting point of the polypropylene you analyzed was lower than that?
A. It was all lower, which tells me it was -- after the manufacturing process it was like 165, I think, roughly, and then it went down from there.
Q. Okay.
A. It varies as a function of molecular weight, it varies as a function of crystallinity.
Do you want to keep this together? Do you know where the start is for this? This is mine.
MR. ANDERSON: I think he flipped it over, so we'll just have to figure it out.
THE WITNESS: I don't want to get us all mixed up.
MR. ANDERSON: There we go.
A. We've got it ready if we need it for something else.

Page 152

BY MR. THOMAS:
Q. We've got too many papers working here. I apologize.
What is a plasticizer?
A. It's generally a low molecular weight material that's put inside of a plastic to make it more flexible.
Q. Do you agree that fat and body tissue will be a plasticizer on polypropylene?
A. Yes, not on, though, in. Only in. It has to get in.
Q. What does that mean when the fat and body tissue soften the polypropylene?
A. It just becomes softer, because -- that's connected with the environmental stress cracking, that's going to get into the polymer and start swelling the chains.
Q. Are you familiar with the concept known as toughness?
A. Yeah.
Q. What is toughness?
A. It's resistance to wear.
Q. Is implanted mesh tougher than pristine mesh?
A. Not seen the measurements, so I don't

Page 153

know.
Q. Have you ever analyzed the question of whether implanted mesh is tougher than pristine mesh?
A. No.
Q. What does it mean if implanted mesh is tougher than pristine mesh?
A. Well, it just means it might be tougher in the sense of, I would use the term -- I'm more like using the term rigid in this case, that would probably also be considered as part of this tougher thing. But it also would make it -- if it's more rigid, it's going to make it more difficult to move in the body, and the patient will have more difficulty doing exercise and the like with that type of thing.
Q. If it's tougher --
A. It's tougher --
Q. -- it's less resistant to be brittle and break, isn't it?
A. Well, we also -- yes, but we also have to consider based on our -- again, back to our SEM photographs, we also have to consider there appears to be two distinctive layers here, there's a surface layer which is cracking and

Page 154

there's an underlying layer which is -- has not yet cracked. So the bulk material could be tougher, while the surface layer is more brittle, at the same time.
Q. Okay.
A. So I don't know what to make of your term because you're lumping it in the bulk, you know, as the entire fiber. And I'm looking at two fibers, the surface region and then the underlying region, which is not cracked yet.
Q. Just to be clear, they are both parts of the same fiber, aren't they?
A. They almost look like two separate fibers.
Q. Okay.
A. And there's publications which indicate the same.
Q. Did you cite those papers in your report?
A. Yes.
Q. Which papers are we talking about now?
A. Well, let's see if I can find it for you quick. You'll have to bear were me while I find it.
(Witness reviewing document.)

Page 155

A. I've got it, I think. This is paper ASIO journal, 1998, Page 199, Mary Celine, "Comparison of in vivo behavior of polyvinylidene fluoride and polypropylene sutures used in vascular surgery."
She's discussing stress cracking at this point. She says "The reason for stress cracking phenomenon in oriented polypropylene monofilaments has been explained by their pronounced skin/core structure." Those are two phases I'm talking about.
Q. Let me stop you there.
What is oriented polypropylene monofilaments? What does that mean?
A. It means it's gone through the dye and it's oriented longitudinally. We can see those lines where it's been pulled through the dye, or pushed.
Q. Does that suggest a stress cracking phenomenon occurs through the extrusion lines?
A. Well, her purpose here is not to talk about that at the moment. It's talking about the bi-component structure.
Q. I understand that.
But as you read that, does that

Page 156

suggest that the stress cracking phenomenon is oriented along the extrusion lines?
A. No. It doesn't say one way or the other. It just says "stress cracking phenomenon in oriented." She's just discussing oriented polypropylene. She doesn't say where the cracks are.
Q. Okay. I understand. Go ahead.
A. "Has been explained by their pronounced skin to core structure. This bi-component structure is created by the differential cooling rates between the external and internal layers of the monofilaments." When it comes out of the dye, the surface cools faster than the inner core. The faster cooling outer surface is going to be less crystalline than the inner core which stays warm longer, has more time to form crystals as it's cooling. So you wind up with two structure types in the filament when you're done.
Q. Are you suggesting by this testimony, Doctor, that it's only the outside of the polypropylene mesh that's degrading, and the inside is fine?
MR. ANDERSON: Objection.

Page 157

Go ahead.
A. I'm not suggesting any such thing.
I'm suggesting that the outer core is chemically less crystalline, and hence more stress cracking susceptible, than the inner part. The inner part would still be susceptible over time depending on the degree of implantation in the body to oxidation.
We have two different things going on at the same time, two layers. There are actually two different kinds of polypropylene, although that wasn't the intent in the manufacture I'm sure, but that's what you wind up with.
BY MR. THOMAS:
Q. Each of which will require a breakdown in the polymer to degrade as described?
A. Each of which --
Q. Sorry.
Each of which would require a breakdown in the polypropylene in order to degrade as described?
A. Right. And the surface layer being less crystalline would also bleed out its antioxidants faster, it's more amorphous, and so

Page 158

it's going to tend to degrade first. And that's what we invariably see in the SEMs, we see a surface cracking and removal.
Q. In your analysis of these explanted meshes, did you ever see a crack all the way through the mesh?
A. I don't think we did. But I've read about them in the literature, I just never saw one in the 23 samples we ran, 24 with Batiste.
Q. Do you have any recollection -- strike that.
Do you know the greatest crack that you observed in any of the meshes that you reviewed?
A. Do I --
Q. Are you able to point to me the biggest crack on any of the meshes and quantify for me how much that crack is compared to the rest of the mesh? I don't want -- if you don't know it, I don't want you to go look.
A. There is a range, certainly.
Q. Can you quantify in measurement?
A. Standing here without looking at the pictures, no.
Q. Is there anything about the pictures

Page 159

that allows you -- strike that.
Did you measure the cracks as a part of your work in this case?
A. No. Actually the entire surface was cracked in many cases, so the entire surface would simply come off.
Q. Let's go to Page 60 of your report, please.
This is the differential scanning calorimetry?
A. Calorimetry.
Q. Calorimetry. Thank you. We've talked around this a lot today.
Would you tell me exactly what this is and what it measures?
A. DSC is a technique that -- where you put energy into a pan, against a standard pan in the other side, and you measure the rate of heat absorption or dissipation of a sample as the temperature rises or drops. You can both heat and cool it.
Q. Okay. And tell me how you set out to measure those things with the DSC methodology?
A. Well, a portion of the sample was put into the tube, into the sample pan, and then the

Page 160

temperature was raised in a heat cycle which is listed in Table 4, heating conditions. First heat we went from minus 90C to 200C at 10 degrees C per minute. Then we cooled from 200 back to minus 90 at 10 degrees C per minute. And then we reheated a second heat from minus 90 to 210 degrees C per minute.
The first heating cycle looks at the form of the material as received. And then the second heating cycle looks at the innate material itself, heat history of the material erased, so all the samples then go to what's called a common heat history. They may not all have a common heat history in the first heat cycle, but, of course, that's the way they actually are in the body so that's the most important one to look at is the Delta H and the melting point, the first melting point in the first Delta H.
Q. In Table 5, did you provide data for all of your explant samples?
A. Let's see. No, there's 15 samples, we had 23. So there were seven that weren't run.
Q. Is there a reason why you didn't test them all?

Page 161

MR. ANDERSON: Objection. Asked and answered.
Go ahead.
A. I remember we didn't need to run all the samples to show the trends, number one.
And number two, some of these cases there simply wasn't enough material to run.
BY MR. THOMAS:
Q. Let's go to Page 66, please, the FTIR microscopy. Let's talk about what FTIR microscopy is. Tell me what that is, please.
A. An FTIR microscope, FTIR instrument, you radiate the sample with infrared radiation. Each type of chemical bond in a molecule will absorb infrared radiation at a different wave length. So when you run across a range of wave lengths, typically from 4,000 reciprocal centimeters to 5 or 600 reciprocal centimeters you get a picture, a literal picture, to a chemist anyway, a picture of the bonds in the molecule that you're looking at.
Q. Now, when you do FTIR analysis, do you generally have a reference against which to measure what you find to match up?
A. That's always run with references. We

Page 162

always run -- to make sure the instrument is running fine, usually a polystyrene standard is run to make sure all the bands come out where they should come out. And then CO2 is removed with a nitrogen purge so you don't have an artificial CO2 peak. That's SOP. That's all in the SOP.

Q. Okay. Do you then have a polypropylene reference point against which to compare your findings that you shoot here to see how they match up?

A. Well, we have polystyrene -- polypropylene reference spectra, so -- and we run the standard polypropylene mesh, which is, in fact, pure polypropylene. So we compare that.

Number one, the polystyrene shows the instrument is behaving good, up to standard, and then the polypropylene is run, it's compared to a known polypropylene spectrum. So if we were to run the mesh and the peaks looked funny we would have caught that. Although that's never happened, because if the polystyrene standard comes out right, it's telling you the machine is working normally.

Page 163

But even if it did for some crazy reason, between the time we ran the standard and the time we ran the polypropylene, we'd immediately flag it because we have polypropylene standard spectra around.

Q. Is the goal of running the FTIR to determine the extent to which what you're testing matches up against what you're looking for; that is, particularly here that you're testing the explanted mesh to determine the extent to which it's consistent with the polypropylene that's supposed to be in the mesh?

A. Yes.

Q. And there are standards against which you measure what your findings are?

A. Correct.

Q. And there will be a standard -- there are a number of different companies that make standard polypropylene spectra against which you could measure your findings?

A. Yes. But we don't need that because we use the spectra, or the known spectra from like Sadtler Library of spectra, I will simply look up what I'm getting versus a known standard, and those two have to match. If they

Page 164

don't match I know I've got a problem, and I stop and fix it, we don't continue.

Q. Believe it or not, I think we're saying the same thing.

A. Hopefully so.

Q. I don't use the same words you do.

A. If you'd like to see the standard, I've got in my book over there. I'll be glad to show it to you.

Q. Which standard did you use, the Sadtler?

A. The Sadtler.

Q. I don't need to see it.

Do you call that a standard? What's the technical term for that?

A. No, I call it a check. It is a type of -- it's part of our SOP. But the standard is the polystyrene, it's always run.

Q. The Sadtler reference that you talked about --

A. Is polypropylene.

Q. And it would be the same sort of spectrum that appears on Page 67 of your report?

A. Exactly.

Q. And you would measure the Sadtler

Page 165

standard for polypropylene against what you find to see if it matches what you find?

A. That's right. In other words, for isotactic polypropylene, which is what Prolene is, we have 841, 973, 997, and 1166 bands, those are the isotactic bands. It's a fingerprint, we call it, of polypropylene, and particularly of isotactic polypropylene.

Q. Do you know of any polypropylene standards that have a spectra for oxidized polypropylene?

MR. ANDERSON: Objection.

Go ahead.

A. I've seen them.

BY MR. THOMAS:

Q. Did you attempt to -- where did you see them?

A. The Sadtler Library. There's a chapter on polypropylenes, and some of them are oxidized and some aren't.

Q. Okay. Have you read about FTIR spectra for oxidized polypropylene?

A. I've just seen them in the Sadtler Library.

Q. Did you consider utilizing spectra for

Page 166

oxidized polypropylene when you conducted your FTIR analysis in Lewis and Batiste?
A. No. I used more of the literature, the Clavés, the Ostergards, and Wood, the current Wood paper and others. They all run infrared of polypropylene.
Q. Why didn't you use the standards which have oxidized polypropylene against which to measure your findings?
A. Well, those were -- those were bulk polypropylenes, this is fiber. So I didn't really have any fiber standard spectra to use anyway. So I guess I could have used them, wouldn't have hurt, wouldn't have made any difference, I don't think.
Q. Why not?
A. Because I already had them from the other literature.
Q. But you are measuring something different with oxidized polypropylene than you are with regular polypropylene by your own definition, correct?
A. Right. As shown in the literature I already have.
Q. The literature you're talking about is

Page 167

Clavé?
A. Yeah, Clavé and there's others. Wood is another one, that's 2013.
Q. Is that contained in your report?
MR. ANDERSON: Yes.
A. I think so.
BY MR. THOMAS:
Q. May I see that, please?
A. Sure. If you want, I'll make you a copy.
Q. We'll take care of that later.
Just for the record, this is the Journal of Material Science, 2013, 24:1113-1122, A.J. Wood, "Materials Characterization, Historical Analysis of Explanted" -- I've seen this before -- "Polypropylene PTFE and PET Hernia Meshes."
You're referring to the FTIR spectra on Page 1117, is that correct?
A. Yes, sir.
Q. And 1118?
A. Yes, that's part of the paper.
Q. So you relied on this rather than the standards in Sadtler or others that may have FTIR spectra for oxidized polypropylene,

Page 168

correct?
MR. ANDERSON: Objection. Form. Go ahead.
A. I certainly could have used those. I don't see it makes any difference. I'm using published literature, recent published literature here, so I feel very safe. I mean I could have used the Sadtler Library, sure.
BY MR. THOMAS:
Q. Well, if the Sadtler Library gave you a different result, you'd be concerned, wouldn't you?
A. But it's not going to. I'm confident sitting here it's not going to give me a different result. I'll go get the spectra and show you, glad to.
Q. The range of absorption regions identified by you as being indicative of oxidation are 1730 to 1680, is that correct?
A. Right. That would include acids around 1700, ketones around 16 -- 1710, 15, and then aldehydes around 1730, esters around 1740.
Q. Do you have anything -- did you find anything in your FTIR analysis of evidence of oxidation in the range of 1730 to 1680?

Page 169

A. It was covered up by the protein that was in the coating, or part of -- I guess you could say coating the fiber pieces.
Q. So is the answer no?
A. The answer is no.
Q. Now, when you run these FTIR samples, you set the machine, the machine reads it, and then the machine is what identifies those areas that are significant and calls them out with numbers, is that right?
A. The frequencies of each band, yes, the machine calls out, yes.
Q. The frequencies of each band?
A. Yes.
Q. So the numbers that appear, for example, on Page 69, along with the spectra there, those numbers are placed there by the machine based upon your calibration of the machine about what's significant. Is that fair?
A. Well, it's simply identifying -- the machine identifies the peaks and labels the numbers. I have to interpret what it means.
We also have -- the computer these days can make estimates and look for matches, too.

Page 170

Q. Okay. On Page 69, you've identified this area at 1757 as being significant, is that right?
A. Right. There's also another region I'd like to mention, it's a little bit subtle, is that shoulder that's at the base of the 1656 peak, towards the left side of it, that would be the 1740. The machine didn't pull it out because there's not a baseline, not a valley in there for it to see. The machine requires a valley to see. But the human eye can see it.
Q. I see.
So that shoulder is something --
A. That's the 1740.
Q. -- that the machine didn't find, but you find?
A. Right. The human brain can still be a machine occasionally.
Q. I see.
A. And if I had taken this sample and treated it with sodium hypochlorite, for example, then we would have gotten rid of the 1656 and the 1541 bands, which are the protein bands, because we have destroyed the protein or the biofilm that was part of the particle or

Page 171

coating the particle, the bulk of which was polypropylene. And then I would have seen only polypropylene, what's left.
This figure that's shown here represents -- keep in mind the carbonyl bands are much stronger than alkyl bands. So the fact that they're roughly the same size suggests to me that this material, as I'm looking at it here, is about 75 percent polypropylene and 25 percent protein, thereabouts, plus or minus a little. And it's oxidized, because I have the 1740 and the 1757. And there may be a 1730 and a 1715 that I can't see because it's buried under the 1656 band, which I could see if in the future we choose to do any more -- like sodium hypochlorite.
Q. Page 72. "Molecular weight is often a crucial factor in determining material properties."
Did I read that correctly?
A. Yes, you do.
Q. What is molecular weight?
A. It's really a measure of the number of repeat units in a given polymer molecule. Monomer is the starting material, usually a

Page 172

liquid or gas, in the case of polypropylene, and then as they monitor units, fuse together, the chains become longer and longer, and then you have eventually a polymer -- generally the start of what we call a polymers around, it's a bit of a range, but we generally consider anything above 2000-ish molecular weight of daltons to be a polymer, albeit a very low molecular weight polymer. Most commercial polymers are hundreds of thousands to millions.
Q. Of what significance to molecular weight is a breakdown of the polypropylene polymer, a change in the polypropylene polymer, will it change the molecular weight?
MR. ANDERSON: Objection to form.
Go ahead.
A. I'm sorry, can I rehear it again?
BY MR. THOMAS:
Q. The polypropylene polymer is broken, the chain is broken.
A. Okay.
Q. Will that change the molecular weight?
A. It will lower it.
Q. Page 80. After doing your analysis, you conclude in your scientific opinion that

Page 173

"The control and explant samples do not show a significant difference in molecular weight."
Correct?
A. That's correct.
Q. Doesn't that mean that there's no evidence in your molecular weight analysis that polypropylene is degrading?
A. It might seem so at first consideration. But remember, the only part of the polymer that seems to be degrading based on the SEM photos is the surface.
So GPC is a bulk technique, I had to dissolve the inside undamaged region as well as the broken pieces, but I get one sample. The total mixture dissolved.
So number one, the effect of the damaged surface -- my point here is I think if we could measure the surface we would see a loss in molecular weight, but I had no way to get enough pieces to measure the molecular weight of only the surface pieces like I did for the infrared spectra.
Q. Aren't you speculating what you find?
A. I am.
Q. Until you have the opportunity to test

Page 174

as you've described, the fact that your molecular weight testing does not show a significant difference in molecular weight suggests that there's no degradation of the polypropylene. That's the best scientific conclusion you can reach in this data, isn't that true?
A. It's one of the conclusions, yes.
Q. It's --
A. It's not the only one.
Q. It's fair to say -- okay.
Now, has Jordi Labs analyzed polypropylene mesh for other manufacturers?
A. I don't run the day-to-day operations anymore, so I would have no way to answer that question. I don't know what has come in.
Q. Do you know?
A. I do not know.
Q. Do you know whether Jordi Labs analyzed Bard mesh that was at issue in the West Virginia litigation?
A. I don't know.
Q. Do you know whether Bard mesh has antioxidants in it?
A. I haven't been requested to analyze,

Page 175

so I don't know.
Q. Do you know whether Bard mesh loses its molecular weight upon testing?
A. I haven't seen the Bard mesh, so no.
Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they -- where Jordi Labs, your company, testified the Bard mesh without antioxidants had showed a loss in molecular weight, is that true?
MR. ANDERSON: Objection to form. Assumes facts not in evidence.
A. Say again?
BY MR. THOMAS:
Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they, where Jordi Labs, your company, testified the Bard mesh without antioxidants showed a loss in molecular weight?
MR. ANDERSON: Same objections.
A. I'm unaware. I don't know.
MR. THOMAS: Are you saying it didn't happen?
MR. ANDERSON: I'm saying the way you asked this question, the way you posited it as something that's true rather than asking him if

Page 176

he knows it is an inappropriate form of a question.
MR. THOMAS: Okay.
MR. ANDERSON: If you think somebody from Jordi Labs testified there, then I think that would differ from reality.
MR. THOMAS: I wasn't talking about Jordi Labs testifying.
MR. ANDERSON: That's what it says.
MR. THOMAS: Got you.
BY MR. THOMAS:
Q. Dr. Jordi, are you aware that Jordi Labs conducted analysis on Bard mesh for use by the Plaintiffs in the Bard mesh litigation?
MR. ANDERSON: Objection. Asked and answered.
A. I am not.
BY MR. THOMAS:
Q. If Jordi Labs had analyzed polypropylene mesh used for pelvic floor implants and found a loss of molecular weight in that mesh, would that be relevant to your opinions in this case?
MR. ANDERSON: Objection.
Go ahead.

Page 177

A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on.
BY MR. THOMAS:
Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes?
A. In the Ethicon mesh?
Q. Yes.
A. It obviously hasn't depolymerized if the molecular weight is the same.
Q. So you're not testifying that it's depolymerized?
MR. ANDERSON: Objection.
A. No. What I think is going on is two effects. I think we have an oxidative phenomenon, which I can show you in my report -- I have the report in here somewhere. I can find it quick.
(Witness reviewing document.)
A. Page 6, it's possible to have -- R prime is the radical form of polypropylene. So if you get two radical polypropylene molecules that physically couple, that will double the

Page 178

molecular weight initially. It's degradation, but it's actually going to increase the molecular weight. At the same time we've got beta scission going on, which is decreasing molecular weight. And initially the two effects can more or less cancel out, and you don't see a net change.

Eventually yes, it will depolymerize, but apparently this material hasn't gone that far.

BY MR. THOMAS:

Q. It's the same across every sample that you tested?

A. Yes, in this case, in this particular set of samples it was.

Q. And it's the same with the Burkley seven year dog study?

A. Yes. That's what Dan Burkley said, yes.

Q. Every time you've tested the molecular weight of Ethicon's mesh or gone back and retested the molecular weight of Ethicon's mesh, the molecular weight hasn't changed in a significant manner?

A. No, we don't see it -- it's true, we do not see a --

Page 179

Q. As a matter of fact, there's never been a time where you've analyzed Ethicon mesh used in these TVT products that shows a change in molecular weight?

MR. ANDERSON: Objection. Asked and answered.

But answer it again.

A. That's true. That's correct.

BY MR. THOMAS:

Q. Dr. Jordi, during lunch I was provided with invoices from your office to Mr. Anderson. I'll read these into the record, if you don't mind.

A. That's fine.

Q. Do you want me to do it so you can see so I do it right?

MR. ANDERSON: What are you trying to point out, just amounts?

MR. THOMAS: Just the dates and amounts.

BY MR. THOMAS:

Q. On August the 12th, 2013, invoice 7783, for $11,250.

August the 28th, 2013, invoice number 7846, amount of $5,000.

Page 180

Invoice number 7881 on September 11, 2013, in the amount of $100,418.74.

Invoice number 7882 dated September 11, 2013, in the amount of $13,980.42.

Invoice 7883, dated September 11, 2013, in the amount of $203,470.

Invoice number 7918 dated September 23rd, 2013, in the amount of $45,375.

Invoice number 7882 dated September 11, 2013, in the amount of $13,980.42.

Invoice number 7884 dated September 11, 2013, in the amount of $6,122.94.

Invoice number 7984 dated October the 10th, 2013, in the amount of $28,130.

And invoice number 8035 dated October 28, 2013, in the amount of $28,876.05.

To the best of your knowledge, is that the total of the billing that you've made in connection with your work in this case?

A. To this point, yes. There's no other bills. I'm sure there will be another one coming.

Q. Obviously in your work in this case you've analyzed a number of different explant samples?

Page 181

A. Correct. 23; 24 with Batiste.

Q. Are you able to tell from these invoices the extent to which your work has focused on the Carolyn Lewis case, or is all of this for the Carolyn Lewis case?

MR. ANDERSON: I'm not sure I understand the question. It could be more legal in nature, so due to that I will object.

BY MR. THOMAS:

Q. Are you able to look at these bills and tell me the extent to which you worked on the Lewis specific matter, for example, perhaps the time when you received the Lewis explant separate and apart from the others that you analyzed, and determine the cost that you incurred in analyzing the Lewis explant? I don't know if you can or not.

MR. ANDERSON: I'm just going to object to the form, because I think you've mixed two different things. One is you're asking how much of the work was case specific, and he's a general expert as well as looking at the specific explant of Ms. Lewis.

So if you want us to look at the bill

Page 182

and see just how much the cost was of the testing and the analysis for just Lewis, we will try to do that. But to mix that up and to say how much of the cost related to just Ms. Lewis, as you know at the trial he's going to be talking about all of these things.

So I just want to make sure we're on the same page and that's clear, because your question was not.

MR. THOMAS: Thank you. I thought my question was clear, but that's good.

BY MR. THOMAS:

Q. Can you tell me the extent to which --

MR. ANDERSON: We agree to disagree.

MR. THOMAS: I understand. I'm going to try to ask the question better now.

BY MR. THOMAS:

Q. Can you look at these invoices, Dr. Jordi, and tell me about the Lewis specific analysis that you did, and the cost of that?

MR. ANDERSON: We'd have to get more material to be able to do that. We tried to bring everything in here to be able to do that, we've got lab notebooks to when those days would be as opposed to the billing. The problem is

Page 183

the billing is through a time period, so we'd have to try to look and match up the time period in the lab notebook to when it was received with the time period on the invoice. We're happy to take the time to try to do that.

MR. THOMAS: I'd like to use my time better than that.

I'm going to mark these invoices collectively as Exhibit Number 5.

MR. ANDERSON: Sure.

(Whereupon, Jordi Exhibit Number 5, Group of invoices from Jordi Labs, was marked for identification.)

BY MR. THOMAS:

Q. Dr. Jordi, what are your opinions with respect to the mesh explant of Carolyn Lewis? If you're going to your report, tell me where you're going, please.

A. As soon as I get there and find something, I will.

Page 71. So that's the infrared, one of the shards from Carolyn Lewis. Sample 13674 showing carbonyl band highlighted there in yellow.

There's a second shoulder you can see

Page 184

there next to it. That would be the 1740.

Q. Let's go one at a time.

The first one you said a minute ago, the carbonyl band where?

A. Around 1759. Some of these, there's no valley there, so the machine didn't actually label it. If you go to the next page, 72, it's very similar, you'll see there it does have a slight valley, so the machine calls it 1761. I think we showed another one that was 1757. It's in that region, all of them.

Q. Is there any discussion in your report anywhere, specifically text, about your findings with respect to Carolyn Lewis?

MR. ANDERSON: You mean in one place?

MR. THOMAS: Anywhere.

BY MR. THOMAS:

Q. About "this is what I find wrong with Carolyn Lewis based on this analysis."

MR. ANDERSON: He's pointing to one right now. I don't understand.

MR. THOMAS: I understand that, Ben.

BY MR. THOMAS:

Q. Do you explain anywhere --

A. I explain the principles in the

Page 185

conclusions. It applies to all the explanted samples, including Carolyn Lewis, but not specifically Carolyn Lewis.

Q. Okay. So there are no specific opinions in your report that relate to Carolyn Lewis, is that fair?

MR. ANDERSON: Objection to form.

THE WITNESS: Answer?

MR. ANDERSON: You can answer.

A. Not that I -- no.

BY MR. THOMAS:

Q. Okay. So it's correct that there are no specific opinions to Carolyn Lewis in your report, correct?

MR. ANDERSON: Objection.

A. Well, there are.

MR. ANDERSON: That's unfair.

Go ahead.

A. There are, because it's the photos. You want it text, but it's in the presence of the printed results.

BY MR. THOMAS:

Q. Okay. But you don't describe anywhere in your report what, for example, Figure 81 means to you in your interpretation, correct?

Page 186

A. I describe in general what all these figures like this mean. So if it's a carbonyl for Carolyn Lewis, or it's a carbonyl for any of the other explants, it's the same meaning.
Q. I see.
So when you point out this shoulder on Page 71 in Figure 81 that's not marked in any way, that's something that you see on the drawing, that you're the one who identifies that and can only testify to that because you can see it; fair?
MR. ANDERSON: Objection to the form of the question.
Go ahead.
A. Well, due to my experience reading FTIRs, yes, I can see it. Anyone else with equivalent experience would see it, too.
BY MR. THOMAS:
Q. Well, I'm lawyer and a history major, would you expect me to be able to figure that out?
MR. ANDERSON: No comment.
A. No comment.
BY MR. THOMAS:
Q. Okay. Certainly not apparent to

Page 187

somebody without your training as to what is shown in Figure 81. Would you agree with that?
A. Without training, none of us could read an infrared. We all have to learn it.
Q. What else do you have specific in your report to Carolyn Lewis?
A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through.
Page 48 is the SEM.
Q. Okay. Let's stop there.
On Page 48 you have Figure 59, and that's -- what does that represent?
A. That's the tissue with the mesh imbedded in the tissue.
Q. Okay.
A. And then the picture 60 is of the actual region that they were -- we were able to get -- I was able to get a photo micrograph of the fiber.
Q. Do you know which part of Figure 59 is depicted in Figure 60?
A. No, not specifically.
Q. What is it about Figure 60 that suggests to you that there's degradation in the

Page 188

Carolyn Lewis mesh?
A. The cracking.
Q. That's the perpendicular cracking?
A. The perpendicular cracking. And then we also have a parallel flaking which you can see at the top, at the bend where it goes -- particles getting ready to come off. And there's also tissue on top of that.
Q. Now, is this the portion of the mesh that you tested with FTIR analysis?
A. It is not.
Q. Okay.
A. Remember, we didn't want to cause any stress or strain on these meshes, so we simply sent it imbedded in tissue. For the IR you must remove the tissue in order to get the spectrum.
Q. Okay. What else do you have for Carolyn Lewis?
A. Okay. SEM-EDX, let's find that chart. 58, Page 58.
Q. On Figure 71, you have -- is that a different image still than the one that was on 48?
A. Yeah. It is, yes.
Q. All right. And the J8041 means what?

Page 189

A. That's the job number.
Q. Okay.
A. 13674 is sample number.
Q. And what does this show you?
A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the -- you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box.
Do you see that?
Q. Yes.
A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum.
Now, that's the cracked region, and has a large amount of oxygen. But we also thought that the cracked region also, well, uniformly showed higher oxygen levels, but it also showed higher, many times, phosphorus and

Page 190

sulfur levels. So that could mean phosphate and sulfate which also contain oxygen, so the increased oxygen in that region could have been from buffers as well as just literally the oxidation type oxygen.

So you want to go to region of the polymer that wasn't cracked, there's Spectrum 4. And that is the red one. It's hard to read in the picture but it's -- the red is Spectrum 4. Now you see -- you still see an oxygen peak, although it's lower in the Spectrum 3, but now the sodium is almost totally gone, and the phosphorus and sulfur are basically gone completely.

So what this is telling me is even in the non-cracked region, I have a higher than baseline level of oxygen. If you want to see that in another --

Q. Before you do that, may I ask you another question?

A. Sure.

Q. I don't want to interrupt you.

A. Go ahead.

Q. Spectrum 4 shown in red, are you suggesting that what you're testing in Spectrum

Page 191

4 is pure polypropylene?

A. Yes.

Q. Okay. Without any kind of contamination at all?

A. We got away from the -- you can see this white material here, which would be the polypropylene -- which would be tissue.

Q. Okay.

A. Which you might call biofilm. We'll have to agree to disagree or agree to agree and use both terms interchangeably. So I wanted to get away from that as much as possible, so we ran a cleaner spectra -- cleaner region that didn't have cracks in it.

Now, when I look at this, I see this cracked material in many places is flaked off. You can see the edge over here on the right where the piece has actually come off and it's gone. You can see the edge where it was. And the same is true on the other side. But on this left side of it, it's clean. And then left of it up there's really nothing but straight -- pretty much straight clean-ish polypropylene. So we ran a spectrum of that, and we still saw increased oxygen. But no increased phosphorus

Page 192

or sulphur. That is the increased oxygen that I call oxidation.

Q. Okay. Again, so Spectrum 3 is meant to be testing the oxidized polypropylene, correct?

A. Right. That's why we ran it there first.

Q. Spectrum 4 is designed to testify -- excuse me.

Spectrum 4 is designed to test what you believe to be clean polypropylene?

A. Let's phrase it this way.

Not yet degraded. Not yet cracked. But I didn't know whether -- if it has increased oxygen in it, that means it's on its way to cracking.

What I believe is happening is layer after layer after layer of this stuff is going to crack depending on the implantation time. The first layer is going to go quickest because it's -- remember the outer layer is less crystalline, remember the paper I showed you earlier, and so it's going to go first. And when it peels off, as some of it's flaked off here, then we expose more underlying fresh

Page 193

surface, which then begins to itself oxidize as reflected in the increased oxygen even in that region, which is the red peak for oxygen.

Q. What is Spectrum 2?

A. We just didn't show it.

Q. Did you run the data?

A. Yeah, I could show it. I could get it. I don't have it with me.

Q. It's not in your report?

A. It might be. Do you want to see if I can find it?

Q. Just curious, yes.

A. Glad to try. If we don't have it, we certainly can get it.

Q. It won't be in the controls, will it?

A. That doesn't mean anything, because I've got -- this is LCMS. It's not in exact.

Here we go. Now I've got --

(Witness reviewing document.)

MR. ANDERSON: We'll go off the record while we're looking. Is that okay with you, Dave?

MR. THOMAS: Yes.

(Off the record discussion.)

(Whereupon, a recess was taken from

2:47 p.m. to 2:53 p.m.)
A. He's got a box on the Spectrum 2 so I'm almost sure it's run, so we'll just have -- if you want that spectrum, I don't see it in the -- number one, the reason it's not there is because it's also on a cracked region just like Spectrum 3 is, so what it's going to look like is the higher -- the one in yellow, it's just a duplicate of the one in yellow.
BY MR. THOMAS:
Q. I understand, Doctor. So for reasons I'm sure you understand, I'd like to have a copy of it.
MR. ANDERSON: Yes.
BY MR. THOMAS:
Q. Just so the record is clear, you've searched your files that you brought with you --
A. I can't find it.
Q. -- and you're unable to find the Spectrum 2 data that appears on Page 58 of Exhibit 1?
MR. ANDERSON: Is that correct?
A. That's correct.
BY MR. THOMAS:
Q. Thank you.

Okay. We were talking about evidence that you had specific to Carolyn Lewis.
A. So the net result here is that we have oxygen in the clean looking, undegraded looking region of the fiber that's under the cracked region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked.
Q. Okay.
A. So we'll go to DSC.
Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram.
Do you see that?
Q. No.
A. Table 5, last entry in the table, under heat effusion for TM.
Q. What page are you on?
A. Page 63.
Q. I'm sorry, I was on 62.
A. Go up. First table, Table 5.
Q. Okay.
A. Last line of that table, and then the middle entry is 69.77.
Q. I have that. That's on Page 63 at the

bottom of Table 5 for sample ID number 13674.
A. Correct. So -- and now we compare that with the first heat effusion for the control samples, you can see that they range from 93, 79, 82, 86. Table 7 probably says it best. We do -- for the samples, we had a couple samples that didn't show any cracking on the average of -- FLP for those samples was 86.6 kilograms per gram -- or joules per gram, sorry. And moderate cracking at 81.2, and highly cracked at 75.1. And here we're at 69.77, so we're in that highly cracked region in terms of this measurement.
Q. Does this DSC testing that you did, which you used to suggest that this is evidence of oxidation, does this also capture the extent to which there are any impurities in the sample?
A. I would say, number one, it doesn't necessarily correlate with oxidation, although it could. But it also correlates with possible stress cracking.
Q. Okay.
A. Because there's less crystallinity.
Q. Let me ask this question again.
You are using this DSC data to suggest

that the lower melting point reflects either oxidation or stress -- environmental stress cracking. Does it also capture any impurities that may have been in the sample?
A. If there were impurities in the sample, they would also tend to lower the melt point.
Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities?
A. No.
Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on?
A. The value of her heat effusion is very low, 69.77.
Q. And you're unable to tell me the extent to which that is oxidation and environmental stress cracking as opposed to impurities?
A. Well, I don't think -- we're not talking about oxidation, we're talking about environmental stress cracking. They're two

Page 198

different, totally different mechanisms for degradation of the polymer. Both are degradation, but one is physical mechanical degradation where the chains are forced to part and they crack, and the other is actual literal oxidation. They're different.

Q. Let me ask the question different, because that wasn't what I was trying to get at.

It's fair to say you don't know the extent to which impurities in the test sample may have contributed to the low heat effusion values for Carolyn Lewis as reflected on Table 5 on Page 63, correct?

A. Correct.

Q. Thank you.

What else do you have for Ms. Lewis?

A. FTIR. Page 71, Figure 81, Figure 82. We have, again, the carbonyl that are on 1760 and another one around -- the shoulder is about 1740, that's under that large 1653 amide 1 band.

Q. Okay. Let me stop you here for a second.

Figure 81 says "Microscopy images showing particles recovered from explant sample 13674 (particle 1)."

Page 199

How many particles did you remove from Ms. Lewis's explant?

A. Didn't count them. Lots. The surface sluffs off.

Q. Did you analyze any others? This is noted as particle 1. That suggests to me that there are others that are identified?

A. Right.

No.

Q. No what? No, you don't know, or no --

A. No, it wasn't the only one analyzed.

Q. Do you still have the others?

A. I don't know. I have to check.

Q. Was it your practice to keep those things following an experiment like this?

A. If there was anything to keep, yes. It was very, very minimal samples here.

Q. Are you able to tell me how many particles there are --

A. No.

Q. -- from Ms. Lewis's sample?

A. I'm not.

Q. Anything else from Ms. Lewis?

(Witness reviewing document.)

A. The amount of lauryl thiodipropionate,

Page 200

Table 18, Page 92. The control samples showed anywhere from 71 million counts to 92 million counts. In this case, we also ran formalin treated control samples which showed levels that were right in the middle of the controls, some were higher, some were lower, fit the normal range for controls, indicating formalin didn't extract the lauryl thiodipropionate.

So the level for Ms. Lewis was 611,000 compared to 80 million, so it's about in the 2 percent range left for the lauryl thiodipropionate antioxidant compared to the controls, and the formalin controls.

Q. Okay. Let's talk about Page 92 for a minute.

Here you have control samples again?

A. Right.

Q. Why do you do a duplicate control like you do on 3422128? Do you have do that as a test?

A. Yes. A test to see how reproducible the material itself might be.

Q. Okay. Or how reliable your test might be?

A. Well, I suppose that's another way to

Page 201

look at it.

Q. And --

A. But we ran standards, and we get the same -- we make the injection standards twice, we get the same area, so that's not --

Q. My point being is that for control sample 3422128, you've got 71,633,460, and then you test exactly the same mesh in a different place in the mesh in the duplicate control and you get 96 thousand 522 --

A. 96 million, yes.

Q. Thank you.

-- 96,522,909, which is about 40 percent more than your other control.

A. We could be extracting regions of the mesh that have flaked off the polypropylene that we see flaked off in the IR, and what we're extracting here is a residual, call it clean mesh.

Q. You don't know why there's a 40 percent difference in the test of the same mesh?

A. No. But I would suspect there's a change in the mesh, either because the mesh itself isn't uniform, or because maybe it's

Page 202

because the polypropylene, the cracked polypropylene is gone in that region at that point, and we are just extracting the enriched area only.
Q. Okay.
A. I think that would easily account for that difference.
Q. But do you have a scientific explanation for the reasons why the same piece of mesh tests differently by some 28 million DAs?
MR. ANDERSON: Other than what he just testified to?
BY MR. THOMAS:
Q. Scientific explanations or reasonable scientific certainty, do you have the answer to the question?
A. I think I just gave it, my estimate of the --
Q. Is that your opinion to a reasonable degree of scientific certainty what happened, or are you just positing it as something you need to test?
A. I think it's reasonable, yes.
Q. Reasonable degree of scientific

Page 203

certainty, is that the answer to the problem?
A. Yes. I think it's reasonable degree of scientific certainty with this one. Because we didn't extract -- the formalin didn't do anything to the polymer in this case, showing me it's not coming out of the polymer -- at least the formalin isn't able to extract it out of the polymer because you're right in the heart of the average.
Q. Well, if you look at 3405405, the control is 79, and the formalin control is 10 million less, isn't it? And the same with 3422128, you've got 96,522,000, and the control was 17 million less, isn't it?
A. Do you have any idea, though, what -- how the ratios are working out here? You're talking about a 20 percent change down here, and I'm talking about a 100-fold change up above.
Q. I know that.
A. It's irrelevant.
Q. Except we don't know how long these mesh explants were in formalin, do we?
A. We put these other ones in formalin and nothing happened.
Q. For two days, right?

Page 204

A. True.
Q. Okay. Anything else on Carolyn Lewis?
A. I think we've pretty well covered it.
I think I can show you -- well, one other thing that might be of interest if we look at Table -- go back and look at that table for a minute longer, and just pick arbitrarily 13411, it has 12 million area counts for --
Q. What page are you on, please?
A. Same page, 92.
Q. I put mine away. I have to figure out the pages.
A. Okay.
Q. Okay.
A. So now that's a relatively higher level than any of the others, isn't it, for the antioxidants, so what would I expect to see? I would expect to see less cracking in that sample if I went back and my theory is right, my scientific opinion is right. So let's go look at the SEM photograph for 13411, which will be the actual degree of cracking, and just see if it correlates or not.
Q. What page is it?
A. I'm looking. I'm getting close. It's

Page 205

37.
Q. Page 37?
A. Right. I would expect to see a low degree of cracking due to the high level of antioxidant still there, and there it is. It's minimally cracked.
Q. That's the one photo you have of all this mesh?
MR. ANDERSON: What?
BY MR. THOMAS:
Q. Strike that, I'm sorry.
So you point to Figure 38 on Page 37 as suggesting that -- suggesting what?
A. Minimal, this is what we would call minimal cracking.
Q. Okay.
A. And it correlates with a high level of antioxidant. So it's being protected, doesn't react, doesn't crack. Or it doesn't crack as much, it obviously is still cracking some, but it's minimal.
Q. Anything else for Carolyn Lewis?
A. No.
Q. Let's go now to the Batiste report.
A. Okay.

Page 206

Q. The Batiste report has been marked as Exhibit Number 2.
MR. THOMAS: Just for the record, I just got this late Monday night, and I've had a chance to go through it a little. We'll reserve on this. I know you disagree with that, but we may reserve to come back to ask more questions about this report at a later time.
MR. ANDERSON: I mean I do object to it, because there was an agreement made between Christy Jones and Rich Freese, and they agreed that in the -- in order to help both sides, because everyone has a lot going on, that there was an agreement that you guys wanted to take -- in fact, your attorneys from -- or the attorneys from Butler Snow -- I have to put this on the record. If you're going to say you're going to reserve the right, I'm going to object and I'm going to put the reasons on.
Attorneys from Butler Snow reached out and said "any of the same experts who are going to be in both Lewis and Batiste, we'd like to try to take their depositions at the same time so we don't have to come back and everybody fly around the country and do them at different

Page 207

times." So we agreed to try to do that.
Also the agreement was that within 48 hours of the depo we would get -- we said we'd try within 48 hours of the depo, which we did, to send over the Batiste results.
And that was the agreement between the parties.
MR. THOMAS: I understand. I just --
MR. ANDERSON: So I don't see how you can then reserve your right after your side has already made an agreement, and we're doing it exactly the way your side wanted to.
MR. THOMAS: I'm not sure anybody contemplated getting 278 pages, but I get it. I just need to make that statement.
MR. ANDERSON: After getting a thousand on the others, I would think that would be reasonable. But go ahead with your questions.
BY MR. THOMAS:
Q. Doctor, when did you prepare the final report of Linda Batiste? It's dated October the 28th, 2013, would that be it?
A. The final date I have is October 30th, 2013. It's the same. You've got --

Page 208

Q. (Indicating).
MR. ANDERSON: 28th.
A. Should be the 28th? I guess. We were all -- this was just taken out of the patient, I believe, most recently, so we've been working on it.
BY MR. THOMAS:
Q. Please understand I've got to mark that one, too, just in case there's something different.
A. I don't think you're going to be finding any differences.
Q. I'm hopeful I won't.
MR. ANDERSON: Not a lot I would bet on, but that one I will bet you there's absolutely no differences in that report other than that date.
MR. THOMAS: Just for the record, I'm marking as Exhibit Number 6 what Dr. Jordi had in his file as being the final report for Linda Batiste dated October 30th, 2013. The one that was produced to us that's been marked as Exhibit 2 is October 28th.

Page 209

(Whereupon, Jordi Exhibit Number 6, 10/30/13 Final Report for Linda Batiste, was marked for identification.)
BY MR. THOMAS:
Q. Mine is two-sided, and it's twice as big as yours.
A. Yes, sir. No.
MR. ANDERSON: This is the rest of the data.
A. This is the rest of it.
BY MR. THOMAS:
Q. Just for the record, I didn't realize there was a second set. So we have all of it, the data makes it twice as big as mine, as it should be. Thank you.
Okay. Doctor, do you intend to rely on the testing that you did in the Carolyn Lewis case in support of your opinions in the Batiste case?
A. Yes. They're the same, the same analyses, yes.
Q. My question is a little different. You did 22 plus, 22 or 23 --
A. 23.

Page 210

Q. -- 23 explant analyses of other patients --
A. Yes.
Q. -- that are not included in your analysis in the Batiste case.
Do you intend as a part of your opinions in Batiste to rely on your work that you did in Carolyn Lewis?
MR. ANDERSON: I can tell you as his attorney that's exactly what we're going to do, because there is no report requirement in Texas.
MR. THOMAS: Just asking.
MR. ANDERSON: Let me just finish, because he may not understand the legal ramifications and what's going on as between a state court requirement and a Federal Court requirement. And there is no reporting requirement in Texas state court.
But we did agree, even though there is no reporting requirement, that we would provide data to make it easier for you guys to take a deposition, even though we don't have to provide a report. So we did that, and we gave it to you 48 hours before the depo, like you asked.
So is he going to rely on all of his

Page 211

opinions in this case in Texas? You bet.
MR. THOMAS: Thank you.
BY MR. THOMAS:
Q. The testing that you did in the Batiste case differs from the testing that you did in the Carolyn Lewis case, I think.
A. In what way?
Q. I don't think you did as much.
A. Let me see.
(Witness reviewing document.)
BY MR. THOMAS:
Q. I don't think you did the PYMS in Batiste.
A. Yeah, we did, it's right here (indicating).
MR. ANDERSON: Page 44.
A. Page 44.
BY MR. THOMAS:
Q. That shows you how close we are. Thank you. I apologize.
A. We did the GPC.
MR. ANDERSON: There's no question pending right now.
BY MR. THOMAS:
Q. Was it your goal, Doctor, to do the

Page 212

same testing for Ms. Batiste as you did for the analysis in Exhibit 1?
A. Yes.
Q. Is it appropriate to use the -- strike that.
Can we rely on your analysis in Exhibit Number 1 with respect to the various tests that we've talked about all day today in understanding how you conducted the test for Linda Batiste?
A. It was run the same way.
Q. So any discussions that we've had today about your methodology, your controls, your results in the Carolyn Lewis report, Exhibit Number 1, would apply equally to the Linda Batiste report, Exhibit 2?
A. Yes.
Q. All right. For Linda Batiste, you have a series of fiber mesh control samples. Are these new mesh control samples different from the mesh control samples you analyzed in Carolyn Lewis?
(Witness reviewing documents.)
A. They're the same.
BY MR. THOMAS:

Page 213

Q. Okay. And how can you tell they're the same; by the test numbers?
A. Same numbers. Table 1 on both.
Q. All right.
A. Page 6 versus Page 13 in the Exhibit 1.
Q. Not that this makes any difference to the ultimate test, do you know whether they were all TVT Classics or TVT-Os?
MR. THOMAS: Or do you know the answer to that?
MR. ANDERSON: Three TVT, three TVT-O.
MR. THOMAS: Thank you.
MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons.
MR. THOMAS: Thank you.
BY MR. THOMAS:
Q. I'm looking at the "Summary of Results."
A. Page, please?
Q. Page 3. It says "A series of mesh control samples and one explant sample received by Jordi Labs."
Just for the record, we just

Page 214

established that the mesh control samples are the same control samples that you used for your comparisons with Carolyn Lewis in Exhibit 1, correct?
A. Correct.
Q. And the explant sample is for Linda Batiste who is the Plaintiff in the Texas action, right?
A. Correct.
Q. "Upon handling, it was observed that the explant sample showed some decreased elasticity as compared to the control fiber mesh samples."
Again, this represents the same reporting that you made in the Carolyn Lewis case about your handling of the mesh explant as compared to the control?
A. That's right.
Q. And do you have any recollection in the Batiste matter for comparing the explant to the formalin control samples?
A. Formalin control sample, no, I don't. I felt the explanted material was rigid, and the pristine felt very friable.
Q. Okay. Next paragraph, "Cracking in

Page 215

the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface."
That's the same finding that you made for Carolyn Lewis?
A. Yes, that will be reflected in the photos, SEM graphs.
Q. "Analysis" -- I'm down in next paragraph now -- "analysis of the explanted fiber mesh by GPC-HT indicated that large scale molecular weight degradation had not occurred in the samples."
The same finding that you had in Carolyn Lewis?
A. Absolutely.
Q. And when you say "large scale," the fact of the matter is you found no significant change in molecular weight; true?
A. In this sample we didn't see a change in the -- oh, molecular weight you're saying?
Q. Yes.
A. No, no change in molecular weight.
Q. Okay. Now, here, different from Carolyn Lewis, you find that "the differential

Page 216

scanning calorimetry analysis showed no change in crystallinity for the cracked explant sample compared with the control samples."
What does that mean?
A. That means that the crystallinity didn't change, and the sample won't be more likely to be subjected to environmental stress cracking.
Q. Okay.
A. Any damage we see would have to be oxidative type damage.
Q. So can we eliminate from the Linda Batiste analysis any environmental stress cracking?
A. Yes, you can eliminate the DSC data if you want, because it's going to say there's no change.
Q. Okay. So you have no molecular weight change and no DSC change?
A. That's correct. In this one sample.
Q. I understand.
Do you know when Ms. Batiste had her surgery to remove her explant?
A. I don't know the exact date, no. It was recent, within the last couple weeks,

Page 217

something like that.
Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate."
A. That's right.
Q. What does that mean?
A. That means that 98 percent of it was gone.
Q. Got it.
A. This time we know for a fact, because the surgery was just performed, that it wasn't sitting in Steelgate for months.
Q. Okay.
A. Because it was -- the surgery was performed, and it was immediately forwarded to us as rapidly as possible. So it would have just been a matter of days at room temperature before we got it and could start our work, as opposed to I really didn't know how long the other ones, other samples had been at Steelgate when we started that, but here it has to be

Page 218

short.
Q. Do you know the percentage of formaldehyde in which the material was stored?
A. I do not.
Q. Did you follow the same sample preparation methods we've described?
A. Yes, in terms of removal of tissue and using forceps and disposable --
Q. Why did you choose the control samples that you did in Table 1 on Page 6? Is that the same ones that you chose before?
A. Same ones, yes.
Q. The reason why I asked is because Table 1 on Page 13 shows a number of additional tests being conducted on the other controls.
A. On page what?
Q. Right here. Compare this chart to this chart. They should be the same, shouldn't they?
MR. ANDERSON: Yes, they are.
MR. THOMAS: Right here. All this data is not on this chart.
MR. ANDERSON: Oh, the data, I thought you said the tests that were run.
A. They weren't. That means that these

Page 219

were run again. And the rest of these were not run again.
BY MR. THOMAS:
Q. So --
A. We did another FTIR micro, we did another DSC, another GPCT.
Q. Does this mean you repeated the test for the first two categories, the OM and the SEM?
A. I need to see the billing.
Q. How much of this testing did you do yourself; any of it?
A. I don't -- these days I don't do much myself. I just supervise the lab personnel.
Q. Is it fair to understand that for both Linda Batiste and Carolyn Lewis that others did the work for you and reported to you and prepared your report, and you're testifying based on other --
A. I prepared the report. They gave me their individual results.
Q. Okay. And you are preparing the report and testifying based on the work of others?
A. Correct.

Page 220

Q. And the others would be reflected in the lab notebooks?
A. Lab notebooks.
Q. And billings?
A. Billings.
Q. Do you know the answer to the question about why Page 6 shows in Table 1 the control sample analysis chart is different than it is in Carolyn Lewis which appears on Page 13?
A. I'd have to refer to the lab notebooks. Maybe it's in the lab notebooks. Do you want me to do that?
Q. Well, to the extent that there's other testing -- well, strike that. We'll come back to that.
Look at your lab notebooks and see if you did new testing.
A. Let's see. That would have had to have been --
MR. ANDERSON: That's the old ones.
(Witness reviewing documents.)
A. 10/29.
MR. ANDERSON: Here you go. This is Batiste.
A. Scalpel -- yeah, that's Batiste.

Page 221

MR. ANDERSON: You're looking to see about the OM and SEM, I think.
MR. THOMAS: The reason why the difference of charts.
MR. ANDERSON: Yes.
(Witness reviewing documents.)
A. So this is all Batiste. There's no indication of any reruns of those standards, of the controls in here, so...
BY MR. THOMAS:
Q. Is it just an omission?
A. I think it may just be an omission.
Q. Okay.
A. 3422128.
Yeah, I think X is up here, that's correct. I think it's an omission. We'll have to correct the table.
Q. Okay.
A. It would have been the same data.
Q. Do you remember, given that this report is dated today --
A. I'll tell you what we can do. We can pick a control sample here and just see if the picture is identical.
Q. Okay.

Page 222

A. That will be a good indication.
I'm sorry, can we go off the record a second?
MR. ANDERSON: We don't have to go off the record. Just don't talk while you're looking.
(Witness reviewing document.)
A. That picture looks identical, Figure 4 looks identical to Figure 5 here, which is the same control.
BY MR. THOMAS:
Q. Just for the record, you're referring to Exhibit Number 1, Page 20, Figure 4, to Exhibit Number 2, Page 12, Figure 5?
A. Right.
Q. So it's your best judgment, based upon your review of those documents, that you're using the same control information for both studies?
A. Here would be a more definitive picture.
MR. ANDERSON: Just answer his question.
A. I'm sorry.
BY MR. THOMAS:

Page 223

Q. So it's your best judgment, based upon your review of those documents, you're using the same control information for both studies?
A. It looks that way. 159, you see --
MR. ANDERSON: Do you feel like you've answered his question that you're using the same controls?
THE WITNESS: Yes.
MR. ANDERSON: Okay. Then we'll move on to the next one.
BY MR. THOMAS:
Q. Now if you go to Page 9, Page 9, Figure 3, does this depict the Batiste mesh as first received by you and then separated into tissue and mesh as you did with the mesh in Carolyn Lewis?
A. It does.
Q. And did you follow the same procedures?
A. We did.
Q. And did Mr. --
A. Adi Kulcarni. Yes, I watched him do it.
Q. Okay. Do you recall making any findings different -- I'm up to Page 11 right

Page 224

now -- any findings different for Linda Batiste about your observations of the mesh?
A. Anything different?
Q. From what you found with Carolyn Lewis.
A. Oh, sure, we've already specified one difference. The DSC didn't show --
Q. That was a bad question.
A. -- the decreased Delta H.
Q. Let me start over again. Strike that. I better do it the right way.
Let's go to Page 8 -- excuse me. I'm sorry. Page 14, Figure 8.
In a number of places in Exhibits 1 and 2 there will be figures with numbers that are shown on there. Here on Figure 8 there's Figures 1, 2, 3 and 4 in red on the mesh.
Do these represent places where, what, scanning electron microscopy was conducted, or do you know?
A. I don't know.
Q. So like on the next page, on Page 15, Figure 10, there are red numbers 1, 2, 3, 4. Do you know what those represent?
A. Well, I can look at the EDX and see if

Page 225

the numbers -- if we have four sites on EDX, that would be the likely -- if there's going to be any correlation, that's what it would be, go find this sample number.
Q. When you say "EDX," the data that you have in your EDX analysis?
A. Yeah. But I don't know, with a control like this, I don't know why that would -- it would make no sense, so I doubt it. But we can check one sample.
Q. Check to make sure.
A. 13161.
It's not here. I don't know what it means.
Q. Okay. And just so we're clear, if you go back to Carolyn Lewis, let's go to Page 24 of Carolyn Lewis. Figure 11, again samples 13162, and there are numbers in red, 1, 2, 3, 4, do you know what those represent?
A. No, I do not.
Q. Okay. If you go to Page 18, please, of Batiste, Exhibit 2, Figure 16. Is this the photograph -- strike that.
What is that? What is Figure 16?
A. That's an optical micrograph.

Page 226

Q. What is that?
A. Photograph of not the SEM, but just a regular optical microscope of the fiber mesh with tissue imbedded in it.
Q. And what is Figure 17?
A. That's a low amplification SEM.
Q. Of the same thing that's depicted in Figure --
A. Right.
Q. Excuse me.
Is what's depicted in Figure 17 the same thing that's depicted in Figure 16, just by different medium?
A. By different methods.
Q. Methods.
A. SEM versus optical.
Q. And as you look at Figure 22 on Page 21, and Figure 23, how would you describe what you see in Figure 22?
A. It looks like greatly cracked material where some of the material has actually flaked off, getting clear under regions underneath.
Q. In your cast of characters -- excuse me.
In your description that you used in

Page 227

Exhibit Number 1 as not cracked, moderately cracked, or cracked, where does this fit?
A. These photos here I would call severely cracked.
Q. Considerably cracked?
A. Considerably or severely, you could use either word.
Q. Okay. Let me ask this question.
You've used a number of different ways today to characterize the cracking that you've seen, and you've broken them down into categories in different places in your report.
What categories of cracking do you deem to be relevant to your analysis on a comparative basis across these mesh?
MR. ANDERSON: Objection. Asked and answered way long ago.
But answer the question again.
A. Minimally, not cracked, minimally, moderately, and then major cracking, or extensive cracking.
BY MR. THOMAS:
Q. What qualifies -- how would you describe something that's minimally cracked?
A. Where I just would see like -- I did

Page 228

show you that one a while ago in the other set where the material was correlated with that large antioxidant level. Was it 411, 411 or something like that?
Q. That's exactly right.
A. I think it was 411. Yes, 411. That's minimally.
Q. What page is that?
A. 37.
Q. That's in Exhibit 1.
And that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair?
A. Fair.
Q. All right. What is moderately cracked?
A. That might be moderate right there (indicating).
Q. What page?
A. 38.
Q. Page 38. Are we in Exhibit 1?
A. These are arbitrary categories, of course, that's why it's very difficult to put absolute numbers on these. But that certainly

Page 229

is cracked more than the 411 sample.
Q. So on Page 38, sample 13412, you describe as being moderately cracked.
What is it about Exhibit 40 on Page 38 of Exhibit Number 1 that qualifies that as moderately cracked?
A. Particularly on the right side of the picture, the cracks are somewhat weak looking, they're not deep into the sample.
Now, there are a couple of places there, this is what makes this so difficult, there are a couple of places on the left side where I would call it certainly more severe cracking, what they're not -- they don't represent a large portion of the surface.
Q. So the cracks that you're referring to are less than a micron in width?
A. Scale is 100-micron, yes, in that order.
Q. And for Ms. Batiste on Page 21, Figures 21 and 23, how would you describe that cracking?
A. Page what now?
Q. 21.
A. Well, you have to look at several of

Page 230

these photos taken together to get kind of like an average.
Q. Okay.
A. If I look at -- if I look at Page 20, I might call it moderate. But if I look at Page 21, these are different regions of the same sample, I'm going to call that severe, because of flaking.
Q. Is it the flaking that makes it severe?
A. Flaking, yeah, because the actual polymer is degraded so badly it's coming off the surface.
Q. All right.
A. It's also the depth. If you want to see the depth, Page 23 shows you the deep cracking that hasn't yet flaked, but you can see it's just dying to flake off on Page 23.
Q. Just so the record is clear, that's a higher magnification than the early ones? It's 450 times, right? Page 23 is 400 times, is that right?
A. Yeah. So I would call this moderate to severe.
Q. And is it the number of cracks?

Page 231

A. Number of cracks, the depth of the cracks, and whether or not it's flaked all enter into the -- flaking tends to --
Q. How are you able to measure the depth of the cracks? Or is this just by total eyeballing it?
A. It's total eyeballing at this point, because you can't really -- until you see the pieces come off, and then they look like they're several microns.
Q. As a practical matter, isn't it impossible to measure the depths of these cracks because they're so small?
A. Well, to get an accurate measurement, right, looking at this photograph I can't tell you exactly how many. But the depth is at least as great, it would appear here, as the width.
Q. So a little less than a micron?
A. Well, I would say that's more like 2 microns, that crack.
Q. Okay.
A. Some of -- this one might be 2 to 3, some of them are 1. They're variable.
Q. Okay. And you would expect a similar depth to that 1 to 3 microns?

Page 232

A. Somewhat.
Q. And that's for severe cracking?
A. Well, it's severe. If I just saw one of those cracks and nothing else and it was clean everywhere else, like if all I saw was this --
Q. What you're doing now is you're --
A. I'm covering up the cracks. But I'm showing you the rest of the fiber. In this case the whole fiber isn't damaged, just the left side.
Q. That's Figure 26?
A. 22 -- Figure 25, sorry.
Q. Figure 25 on Page 22 of Exhibit 2?
A. Correct.
Q. Okay. Figure 25 on Page 22 of Exhibit 2, the cracks that you see on the left side, again are 1 to 3 microns wide. That's 600 times magnification, that's even higher?
A. But you've got the scale here of --
Q. You changed the page again on me. Which one are you looking at now?
A. Page 23, 26.
Q. Okay. Figure --
A. 450X.

Page 233

Q. Page 23, 450X, Figure 26.
A. So that crack there on the -- the big crack in the middle of the left side of that picture looking at the scale has got to be on the order of --
Q. 5 microns?
A. -- 5-micron, something like that.
Q. No way to tell from this how deep it is?
A. You can tell from the -- now you can tell because it's bent upwards. The actual thickness of the polypropylene piece that's about to break off looks like it's 1 to 2 microns.
Q. Okay. But the depth there is not going to be any more than five microns?
A. No.
Q. Probably less?
A. On that order, yes.
Q. Okay. So that's severe cracking?
A. Yes, because it runs, covers the entire --
Q. Okay. Let's go to Page 29, Figure 33. You're conducting the SEM-EDX analysis here, correct?

Page 234

A. Yes. Correct.
Q. And how would you describe the cracking that you see in Figure 33?
A. Moderate in that particular piece.
Q. All right. And Spectrum 2 and Spectrum 3 are shown.
Is there a Spectrum 1?
A. No. Usually just shows two pieces, I don't know why we had three on here.
Q. Do you usually start numbering at 2?
A. I don't know why that was done. It's 2, he may have had a 1 somewhere else, or just didn't renumber them.
Q. If there's a 1, it doesn't show up on the data that appears here, correct?
A. Right. The box and the number correlates with the spectrum you see below.
Q. Right.
What's the difference between 34 and 35?
A. Just a scale-up.
Q. Okay.
A. So we can see the minor elements better.
Q. I see.

Page 235

DSC, we decided there was no change, so there's no evidence of environmental stress cracking?
A. Let me just look at the numbers, but I believe that's correct.
(Witness reviewing document.)
A. That's correct.
BY MR. THOMAS:
Q. So any oxidation that's occurring -- strike that.
So any of the cracks that we see in Linda Batiste is going to be due to straight oxidation?
A. I believe that's correct.
Q. And do you know what caused the oxidation in Linda Batiste's mesh?
A. Well, one cause would be the lack of antioxidant in the fiber, if we find that, which we have to go look at the LCMS analysis primarily.
The other would be the IR results for carbonyls to see if we had oxidation there.
Those are the two primary -- well, and the third is the one I just showed you was EDX. Because that oxygen in the clean regions by EDX,

Page 236

this peak here, that's in the region that isn't cracked.
Q. My question is not what the proof of it is. My question is what caused it.
What caused the oxidation?
A. What caused the oxidation. Well, that would probably be due to the inflammation, among other things, that's in the human body. If the material isn't protected by antioxidants and it's exposed to macrophages and hydrogen peroxide and so on, if there was inflammation, and shards were coming off the particle and inflammation is caused to increase that --
Q. Are you guessing, or is that your opinion?
A. That's published literature.
Q. It's your opinion that published literature stands for the proposition that in the face of inflammation, that polypropylene mesh without antioxidants will degrade?
A. Yes.
Q. And what literature is that?
A. Well, it goes back to --
Q. Is that the Liebert article?
A. Liebert article, it goes back to

Page 237

Oswald and Turi article, as early as '65.
Q. Okay.
A. Williams talks about it in a number of articles.
Q. It's ultimately premised on the suggestion that the antioxidants in the Ethicon mesh have leached out and are gone, correct?
A. Correct.
Q. Right.
And it's only if the antioxidants are leached out and gone that your theory is correct?
A. I don't know that it would mean you couldn't oxidize polypropylene even in the presence of antioxidants. You certainly can. But it retards it.
Q. But you've not studied that question. Your theory and opinion is that the antioxidants have leached out, therefore the mesh is degraded? That's your opinion to a reasonable degree of certainty?
A. It would be a fact in my mind, because we're looking at the actual lack thereof.
Q. Okay.
A. Not assuming lack of, I'm looking to

Page 238

see if we see a lack of.
Q. I understand.
But that's your opinion to a reasonable degree of scientific certainty how this degradation occurred; that is, that the antioxidants leached out leaving the mesh defenseless, and that is the reason why the mesh degraded?
A. Yes.
Q. Page 34 --
A. Yes, sir.
Q. -- on Exhibit 2.
This same value is in Exhibit 1, the typical value for the melt point of polypropylene?
A. Where are you?
Q. I'm right in the middle of the page on Page 34.
A. 34. Okay. Right.
Q. Is it your opinion that the typical value for polypropylene melting is 175 degrees C?
A. Again, that comes out of the book we looked at earlier this morning, Turi.
Q. Do you know whether that is the

Page 239

typical melt point for the polypropylene mesh that Ethicon manufactured and sold?
A. No. We measured, we measured that as well. That's the controls. It's 165-ish.
Q. Okay. My point is; you're not suggesting because it's 165 instead of 175 from the literature that it's more susceptible to environmental stress cracking or degradation, are you?
A. I'm suggesting it's less crystalline.
Q. Okay. Are you suggesting it's more susceptible to environmental stress cracking because --
A. Than the native pellet polypropylene from which the fiber was manufactured, yes, I am.
Q. And are you suggesting that it's more susceptible to oxidation because its melting point is 165 as opposed to 175 and 80 polypropylene pellets?
A. Yes.
Q. Page 43 in your molecular weight analysis.
A. Okay.
Q. It says in the middle of the

Page 240

paragraph, "After you don't find a difference in molecular weight, the environmental stress cracking mechanism does not require a decrease in molecular weight."
I think we've already decided that the mesh -- any mesh degradation for Ms. Batiste is not due to environmental stress cracking; fair?
A. Right.
Q. Okay.
A. So that's why I state we observed cracking in the explant samples due to oxidation in the fiber surface, in this particular sample.
Q. In the PYMS analysis on Page 34.
A. Page 34?
Q. I'm sorry, 44. Thank you.
A. Okay.
Q. Am I correct that there's no analysis of the Santonox antioxidant?
A. Right.
Q. Why not?
A. As I mentioned this morning, in PYMS when you -- if you'll look at Page 45, Figure 46, the antioxidants, you'll see a large -- you'll see the control is the blue, and you'll see a large red peak righter blue is eluting.

Page 241

What that is mostly is polypropylene fragment ions, and it was overwhelming the signal for Santonox R, so we really couldn't get an accurate reading.
Q. Tell me what that means. I don't know how that works. I don't understand.
A. Well, in LCMS you extract the additives, and then you shoot a solution of the extract, so you don't have the polymer to worry about at all.
In PYMS you put the entire sample in, the solid polypropylene piece, or a bit of actual fiber, and then you burn it basically, pyrolize it, and then the pieces go into the GC system column and get separated. But there are sometimes hundreds of thousands of pieces, and sometimes for materials you want to analyze they just get overwhelmed, the material I want to analyze for is overwhelmed by the background is what it's called.
So any estimate we would have made here, we would have got a large peak, it doesn't mean anything because it's got all these other ions in it, which just is flooding the system in that particular time point.

Page 242

Now, for the other antioxidate, the lauryl thiodipropionate --
Q. Let me just interrupt for a minute. Could you have changed your test or changed your materials to test again for Santonox in an effort to capture the concentration of Santonox?
A. You can run single ion, extracted ion chromatography, we call it, that helps. In this case it didn't help enough.
Q. Why does it work in the Carolyn Lewis case for all the samples that you've tested there, but doesn't for Linda Batiste?
A. Don't have an answer for that. I just know this is characteristic of PYMS. LCMS gives -- in this case because we don't have the background, we don't have the degree of problems.
Q. Just so I understand --
A. It doesn't always not work either, it's a matter of a judgment call.
Q. But you got PYMS testing and results in all but four of the samples you tested in Exhibit 1, correct? That's on Page 15 and 16.
A. Oh, Exhibit 1?

Page 243

Q. Yes.
A. Well, I know that one thing that's happened since this work was done was a column had to be changed out.
Q. What does that mean?
A. Well, the column eventually goes, and we have to cycle it out. So another column is -- this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the -- I'm sure of this, that it's being buried under polypropylene fragments.
Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in Exhibit 2?
A. It's a different column, so the selectivity is a little bit different. Quantitation of additives is much more difficult than PYMS than it is -- it's good for detection and confirming the presence of things, it's not good for quantitating anything.
Q. LCMS --
A. LCMS is much better, in general.

Page 244

Q. All right. At this time for the LCMS test beginning on Page 46, there's no formalin control data, is there?
A. No.
Q. So the tests that you conducted in LCMS would not show the extent to which formalin may have confounded your findings?
A. For the Santonox R, that would be true. But for the lauryl thiodipropionate, the standards we've already run clearly were not extracted by the formalin.
Q. You didn't do a formalin control test for Linda Batiste to determine the extent to which formalin would impact your LCMS findings; true?
A. Well, we did it, but it's in reference one. Remember we're going to use these data together. Because we already have two formalin controls in the -- what do you call -- the Exhibit 1.
Q. Okay.
A. So yes, we have controls of formalin.
Q. So whatever --
A. Page 92 --
Q. -- whatever conclusions might be drawn

Page 245

from the formalin control samples and their impact on the antioxidants that may have been present in the mesh apply equally to your findings for Linda Batiste?
A. That's correct.
Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct?
A. Okay. What am I -- on Page 50?
Q. On Page 50, Table 12.
A. Okay. 3422128.
Q. You show that Santonox quantitation, correct?
A. In that table.
Q. Why did you choose the 4,430,284 figure as the control against which you compare Santonox?
A. It's in the middle. Hang on, let me check this again.
Q. I don't see that value in the controls on Page 96. It should be there, shouldn't it?
A. 3422128.
Q. That value is different, isn't it?
A. Yes.

Page 246

Q. Do you know why that is?
A. That would indicate to me that he reran the control. We extracted it.
Q. I thought we decided a moment ago they didn't.
A. Most of the tests they didn't. I can check that.
Q. Okay. So what this says is that we have yet a third value for this --
A. Standard.
Q. -- control --
A. Control.
Q. -- test.
Not standard, it's a control?
A. Control.
Q. So the value here of 4430284, you think is a new test of mesh tested with Carolyn Lewis?
A. Correct.
Q. As you sit here today, do you know any other new tests that were conducted for Linda Batiste in order to do -- on the controls that were used to compare the Linda Batiste mesh samples?
A. Let's check the control in Table 11

Page 247

just to see. All right. Let's go back. 34221228.
Q. What page are you on, please?
A. 92 and 49. It's the number of -- it's the same standard run for the lauryl thiodipropionate, but the number is different again. So it's certainly right on the same range, but it means it's rerun, same thing.
Q. So the dilauryl has also been rerun?
A. The standard has, yes, along with the actual sample.
Q. Where are you looking to see that?
A. Table 11, lot 3422128, Page 49.
Q. And that's a value -- you have two of those values from the first one on Page 92, and on Page 92 of Exhibit Number 1 you obtained a value of 71,633,460?
A. Mm-hmm.
Q. And a duplicate result of 96,522,909, and this is a third value for the same piece of mesh at 82,091,505.
A. Right, between the other two.
Q. Okay. So do you know of any other new control testing conducted for Linda Batiste?
A. I do not.

Page 248

Q. Would it be -- do you know why this new control testing was conducted for Linda Batiste?
A. Well, the response of the detectors, the HPLC type, LCMS detectors can change over time, so it would just be good lab practice, since this was run at a different time from the other samples, to rule out any change that way. Whereas an SEM photograph is an SEM photograph, it wouldn't matter, so there would be no need to rerun those.
Q. Tell me again what it means to change the column.
A. Well, when you're doing chromatography, columns wear out, and you have to periodically change them. The peaks get broad, they get narrower, materials start to bleed into -- peaks start to bleed into one another, and it's just time to change the column. It's just normal -- what we call normal maintenance, like changing the oil in a car.
Q. How do you determine when it's appropriate to change the column?
A. You have standards that you run, and you look for resolution standards. And when the

Page 249

resolution no longer meets the minimum standard, it's time to change it. It's part of the SOP.
Q. How often do you change the column?
A. When? I don't know how to answer that.
Q. Every 2,000 miles?
A. It's when it fails, when it fails a test.
Q. Okay.
A. It's checked every time we run samples to see that the minimum resolution is there, or it's changed.
Q. Before you sat down to give your deposition today, did you realize that the controls had had additional testing conducted on them?
A. These controls here?
Q. In Exhibit 2 for Linda Batiste.
A. No. In all honesty, no.
Q. Okay. Fair to understand that a doctor would have to give any opinion about the extent to which any degradation in the mesh that you have found would cause Ms. Batiste any physical harm or other health problems?
A. No, I would defer to them for the

Page 250

actual physical type damage, it's not -- it's beyond, out of my field.
MR. THOMAS: I'm going to want copies of everything but the Burkley deposition. The lab notebooks, the articles, and the SOPs.
MR. ANDERSON: Just leave them all there for right now.
MR. THOMAS: What's the best way to do that, Ben?
MR. ANDERSON: Good question. The lab notebooks obviously can't leave, so we would just have to run copies of those for you. All the other things we can run copies for you. Or we can give them to madame court reporter and have her run some copies.
MR. THOMAS: I don't care just as long as I get them. Whatever makes sense. I think you and I can figure this out.
MR. ANDERSON: Okay.
BY MR. THOMAS:
Q. Doctor, you brought a number of things with you to the deposition today including a number of books, a copy of the deposition of Dan Burkley.
I have here three laboratory

Page 251

notebooks. What are these?
A. These are the laboratory notebooks telling the sample preparation and what was done to the samples, and by who, and on what date.
Q. What's the purpose of a laboratory notebook? What are you trying to capture in a laboratory notebook?
A. We're trying to capture when things were done so that we know who did what so we can go ask questions of proper people so we have a paper trail for the way the sample was handled.
Q. Is it fair to understand one of the goals of a lab notebook is to provide enough information so that somebody coming behind you can understand what you did and recreate it if necessary?
A. Yes. Absolutely.
Q. And the lab notebook has a number of names in here. Are these the people who's samples were tested, do you know?
A. You'll have to show me the specifics.
(Witness reviewing document.)
A. Yes, those are the sample --
MR. ANDERSON: Hand it back to him.
"Yes" answers the question.

Page 252

BY MR. THOMAS:
Q. Do you know whether all of the samples were tested?
A. No. Some of the samples weren't tested.
Q. Do you know why some weren't tested?
A. There were several that weren't, two or three maybe that weren't tested because they were mixtures of multiple products, and we didn't want to run those.
Q. Okay. Is there any way to tell from the entries in the lab notebook, to your knowledge, about the reasons why certain ones weren't tested?
A. Here's one that wasn't run and it wasn't run because -- I'm assuming it wasn't run because sample received with no formalin. We didn't run it. We didn't know what would happen to the sample in the absence of preservatives so we just didn't run it.
Q. And who was that?
A. We have several here. Cynthia Simpson, and Alma Sarcia.
MR. ANDERSON: Garcia.
A. Garcia. Sorry. JPG240-241,

Page 253

JPG1362-1363.
BY MR. THOMAS:
Q. And did you have anything to do with the decision not to test those products?
A. Well, it would be standard operating procedure that if something comes in in a non-standard format in a situation as -- well, any situation, we wouldn't run it without the client's approval. We'd have to go back to them and see if they still wanted to run it, because otherwise --
Q. Did you, in fact, raise that issue with anybody about whether the sample should be tested because it did not come in formalin?
A. I think the analysts probably got together and discussed it, yeah.
Q. Did you have any role in the decision --
A. No, I didn't. That's standard operating procedure.
Q. Let me finish my question, please.
Did you ever any role in the decision not to test the mesh samples that did not come in formalin?
A. No.

Page 254

Q. Were you aware before reading the laboratory notebook today during your deposition that a decision was made not to test some of the mesh samples because they didn't have formalin?
A. Yeah, we've discussed that.
Q. Who have you discussed it with?
A. Adi Kulcarni who has been involved in this, and my son Mark.
Q. What did you discuss about that?
A. Just that we didn't feel it was fit to run because they were different, they didn't match normal composition.
Q. Why? They looked different?
A. They were dry, yeah.
Q. Okay. Do you know if they'd ever been in formalin?
A. I assume they had, but I have no way to know that. They're supposed to send them to us in formalin, so you've got to assume they were sent in formalin at some point.
Q. Okay.
A. And it was lost. We don't know when.
MR. ANDERSON: Don't assume things that you don't know. If you know the answer, then you say I know the answer.

Page 255

THE WITNESS: I don't know the answer.
MR. ANDERSON: If you don't know the answer, please say I don't know the answer, okay?
BY MR. THOMAS:
Q. How many samples did you receive without formalin that you didn't test?
(Witness reviewing document.)
A. Looks like two.
BY MR. THOMAS:
Q. And you identified one of them. What's the other one? Can you identify that for me, please?
MR. ANDERSON: He said both those names.
A. I said both.
BY MR. THOMAS:
Q. I'm sorry. Thank you.
Who runs your lab?
A. My son and his business partner.
Q. What's his business partner's name?
A. Patrick Burke.
Q. Is he the person -- is your son the person responsible for all testing conducted by Jordi Labs?

Page 256

A. Today he is, yes.
Q. Has he been for the last two years?
A. Yes.
Q. So any testing that would have come in Jordi Labs to test polypropylene mesh would have been overseen by your son Mark? Is that his name?
A. Yes.
Q. To the extent that questions I asked you before about other mesh that has been analyzed by Jordi Labs, the person who would know about that is your son Mark?
A. Yes. Not me.
Q. How long has it been since you've had hands-on responsibility in the lab?
A. Four, five years now.
Q. And what do you do here at Jordi Labs?
A. I'm involved in R&D. And I act as an expert witness. I review jobs as requested. We try to have three or four or five people review every job that goes out to look for errors, that kind of thing. I'm working in developing new products.
Q. How much of your time is spent consulting as an expert witness?

Page 257

A. Well, generally it's a sideline, this case being a little bigger than most that we've seen.
Q. In the last three months, how much of your time has been occupied by this case?
A. Three months, probably 50 percent.
Q. Okay. What have you done the other 50 percent of the time?
A. Well, as I said, I'm reviewing jobs, I'm working on developing new products, which I've been doing for years.
Q. In the last two years, have you had any responsibility for supervising the activities in the lab?
A. In the last two years?
Q. Yes.
A. No.
Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done?
A. Right.
Q. Is Jordi Labs privately held?
A. Yes, it is.
Q. How many shareholders in Jordi Labs?
A. Two.

Page 258

Q. Who are they?
A. My son and his business partner.
Q. You no longer are an owner of Jordi Labs?
A. No. My son. I wanted to get out in time from the ownership situation.
Q. Okay. And when did that happen?
A. I don't remember exactly. It's four or five years.
Q. How many employees does Jordi Labs have now?
A. Again, I don't know exactly. It changes every day. I'd say 25, 26, around there.
Q. Do you know what percentage of the Jordi Labs work is legal consulting on legal cases?
A. Well, generally it's a small percentage. As I say, right now it's a bigger percentage because of the nature of this case, but it's an unusual situation.
Q. In this stack of documents are a number of reports from an Evans Analytical Group.
A. Right.

Page 259

Q. Tell me what those are, please.
A. The FTIR microscope work was done by Evans in California, and the SEM, SEM-EDX was done by Evans Group in Minnesota.
Q. Is that because you don't have the --
A. We don't have those instruments.
Q. How did you happen to choose the Evans Analytical Group to perform this testing?
A. We've worked with a company called Chemir in the past, they were bought out by Evans, and they're, I think, about a $7 billion company, and they're a very well respected lab, so we utilize their technique that we don't have.
Q. Is it the FTIR data --
A. FTIR microscope.
Q. Okay. So for the FTIR and the scanning electron microscope work, you ship that out?
A. That's correct.
Q. And how did you transport the samples?
A. They were sent by our office staff following the regulations that we -- procedures that were set up and described to us to handle and to keep chain of custody.

Page 260

Q. Do you specifically know how that happened?
A. Not exactly, I don't.
Q. Okay. That's fine.
And what did you do to assure that Evans Analytical Group and -- what's the other company?
MR. ANDERSON: They're both Evans.
A. They're both Evans, different divisions.
BY MR. THOMAS:
Q. Sorry. Strike that.
What did you do to assure that the Evans Analytical Group was capable of performing the work that you asked them to do?
A. We've been working with a gentleman at Chemir, and we've been referring jobs back and forth for years at various times, and he is -- he's really our contact with Evans. We've had tremendous results for a number of years working with -- both ways, he sends a lot of work here, we send some -- we send a lot of work his way.
Q. So the FTIR -- strike that.
So all of the data done by Evans was added to your report without change or input

Page 261

from you?
A. Yes. Basically you have those results. Any changes you can see there. I'm sure there were a few verbal changes, but essentially it's the IR spectra, the IR spectra. We certainly wouldn't have -- we wouldn't even have the capability of changing those spectra.
Q. Okay. Has Jordi Labs ever had an electron microscope?
A. No.
Q. Has Jordi Labs ever had the capability to do the FTIR analysis?
A. Yes.
Q. When did you have that?
A. Oh, probably -- well, we've had it since basically day one of the company at various units. Classical FTIR. Now we have the Diamond ATR system.
Q. You still have it?
A. Absolutely.
Q. Why do you ship this out to Evans?
MR. ANDERSON: Micro.
A. Micro.
BY MR. THOMAS:
Q. I'm sorry. Okay.

Page 262

Has Jordi ever had the capability to do the kind of work that Evans did on the FTIR?
A. No, we have never had an FTIR microscope system.
Q. Who is Scott Bowman?
A. He's the gentlemen that transfers jobs back and between us and Evans, or he sends us work, we send him work.
Q. Does he work for Jordi or work for Evans?
A. He works for himself.
Q. Pretty good gig.
A. It's worked out extremely well for us and extremely well for him. We love his expertise and his ability to get us in touch with the best people.
Q. He's not a -- is he a technical guy?
A. Absolutely is.
Q. Does he do any technical work?
A. No, he just basically is --
Q. He's a broker?
A. He's a broker, a very good one.
Q. So on these SEM analysis reports here that you got apparently from Evans --
A. He may --

Page 263

MR. ANDERSON: Hold on.
BY MR. THOMAS:
Q. -- the numbers appear that I asked you about, you didn't know where they came from?
A. Right.
Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know?
A. They would have had to have been put on by Evans because we couldn't have done it.
Q. Okay.
A. It's their pictures.
Q. Do you have these in an electronic format? I'm sure you do. Digital format?
A. I'm sure we can get them. Adi, again, would know, handles that kind of thing for me.
Q. Did you do all the other testing in-house?
A. Yes, we did.
Q. The documents that I'm going through now are Jordi SOPs, is that correct?
A. Yes.
Q. And these would be the internal procedures that you have that instruct folks in

Page 264

how to conduct the tests that you did?
A. That's right.
Q. Diamond Shamrock Corporation, is this a standard for polypropylene, or can you tell by looking at it?
A. Let me take a look. I can't read it from there.
Q. (Handing).
A. Yes, that's the polypropylene standard spectrum. Isotactic.
Q. When we talked before, I thought we decided you didn't use a standard against which to compare your results, that you used your own training, education, literature.
A. There's no way for me to keep track of everything these people are doing out here now. I'm telling you the polystyrene is the one that's used.
Q. Do you know the extent to which the people in the lab used that Diamond Shamrock standard for polypropylene in connection with their work on the opinions in Exhibit 1 or 2? Do you know?
A. No, because these -- this isn't an SOP anyway. This is just a bunch of spectra. I'm

Page 265

not sure why that's even in there, it's not SOP.
Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene.
What's the document I just gave you there, do you know? Do you recognize that?
A. It's another polypropylene spectrum, J7904.
Oh, let me see the other one again, please.
Q. (Handing).
(Witness reviewing document.)
A. These appear to be spectra of the explants done on our instrument which were polypropylene. We saw lots of noise. This is why we chose to go with the FTIR microscope route. We had to look at the total samples, number one.
Number two, the samples wouldn't lay flat on our Diamond, and they tended to want to bounce around because they were rigid, and so it was difficult to get a good spectrum, it was lots of noise, so we went to where we could go to a high sensitivity technique where we could,

Page 266

number one, hone in on the cracked regions. When you run a sample with an instrument like this, you're running can the total sample, so you're diluting the effect on the cracked regions, you'd be running a combination of cracked and uncracked regions. When we use the IR microscope, you can hone in on any specific region of the fiber we want, that's the advantage. So we decided to go with that technique because it offered us -- for what we needed for this work, it's a far better methodology.

Q. Before I showed you these documents, were you aware that Jordi Labs had tried to analyze in-house --

A. Yes, I was.

Q. -- the FTIR spectra for these explants?

A. Yes, I was.

Q. Okay. And you tried it, and the documents you just looked at are the documents that you generated in-house from your results of your analysis, correct?

A. That's -- I'm sorry, go ahead, ask the question again. I'm sorry.

Page 267

Q. I will mark as Exhibit Number 7 the documents you've just been looking at.

(Whereupon, Jordi Exhibit Number 7, Group of films, was marked for identification.)

BY MR. THOMAS:

Q. And the first page is the Diamond Shamrock standard from Sadtler, S-A-D-T-L-E-R, and then attached to that are FTIR spectra that you all ran in-house with your own capability, at which point you determined that you weren't generating the specificity of the data you needed to make your analysis so you contracted it out for microscopic FTIR?

A. That's correct.

Q. Is that fair?

A. That's fair.

Q. Mark that as Exhibit Number 7.

MR. THOMAS: I won't mark the lab notebooks.

The rest of what I have here are miscellaneous SOPs, the Evans reports, and the Evans reports. Do you want the court reporter to have those, or how do you want to do this?

MR. ANDERSON: What we can do is we

Page 268

can find out if those are extra copies. If those are extra copies, she can take them with her. If they're not, then we'd like to leave them here so that we can make copies, or we can have you take them and make copies. I think I need to make sure they're not originals.

MR. THOMAS: Here's what I'd like to have, you tell me if I can have it. I'd like to have a hard copy and a digital copy.

MR. ANDERSON: Well, I'd like to have a million bucks and retire tomorrow, so if you can deliver I will.

MR. THOMAS: You can't retire on a million dollars, I know you.

MR. ANDERSON: It will last me a couple months.

MR. THOMAS: That wouldn't keep you in Red Bull.

MR. ANDERSON: If you're getting digital -- well, hopefully they have it in digital, then we'll give it to madame court reporter and it will be an exhibit to the depo. If -- that will still be in digital for you, so you need a hard copy. We'll do the best we can. If it's digital --

Page 269

MR. THOMAS: Digital is my first choice, I'll print my own copy. The hard copy allows me to know I have everything. Not because I'm suggesting you're going to do anything with it.

MR. ANDERSON: No, it's easier. I'm a hard copy guy, too. Why don't we figure that out after the depo.

BY MR. THOMAS:

Q. I'd also like a color copy of your studies that you have.

A. You'd like a what, sir?

Q. Color copy so I can capture the highlighting in your studies. Because you brought with you today a notebook of studies upon which you rely for your opinions in the case.

A. Articles, yes.

Q. And you have highlighting and writing on them, correct?

A. Mostly highlighting, yes.

Q. I want versions of those that capture the highlighting.

MR. ANDERSON: Absolutely.

A. Fair enough.

Page 270

MR. ANDERSON: We need to take a break. Let's take a break.
(Whereupon, a recess was taken from 4:39 p.m. to 4:56 p.m.)
BY MR. THOMAS:
Q. Doctor, attached to Exhibit 1 is a part of -- oh, right after your primary report, is your CV. I'm just going to ask you some questions about your career. You can look at the CV if you want to. I imagine you know it pretty well.
A. Where is it here? What page?
Q. It's after Page 102. I bet you it's in the back of that.
A. Appendix. Conclusion.
MR. ANDERSON: After Page 102?
MR. THOMAS: That's where I have it. It will be in that copy right there.
A. All right. That's fine.
MR. THOMAS: We've got it here, Ben.
A. Okay.
BY MR. THOMAS:
Q. All right. Tell me about your education after college, Dr. Jordi. I mean after high school.

Page 271

A. I went to Northern Illinois University in DeKalb, Illinois, worked on my bachelor's degree in chemistry, graduated in the summer of 1967.
Was offered a graduate position there, an NIH fellowship, so I stayed there and worked on my doctorate degree. I finished that in 1973, and actually officially graduated in January of '74, but I'd already left and was already in the US Army at Walter Reed by that point.
Q. You worked at Walter Reed for how many years?
A. A little over three years.
Q. What did you do at Walter Reed?
A. It was a lab tech chemist position. I worked with, as I mentioned, the biodegradable implants, polylactic and glycolic acid copolymers. We had an another project for purification of eugenol, which is used by dentists. I worked on developing methods of purifying eugenol.
Q. You were employed at this time as an analytical chemist?
A. Basically.

Page 272

Q. And your job as an analytical chemist was to do the lab work associated with any issues that might arise?
A. Whatever came up. Whatever projects they wanted support for.
Q. All right. And the extent to which any of these products may be appropriate for use in humans would be something beyond what you were doing in the lab on the bench?
A. Yes.
Q. Okay. What did you do -- you were next employed for six months at Waters Associates. What were you have doing there; more of the same analytic chemist group?
A. Basically Waters at that time was, still is a great company, but by my standards, my personality, I like a company that's personable with their customers. They had a philosophy at that time that they would work to solve the customer's separation need and earn the sale of the HPLC instrument through providing the solution of their separations problem, and so my job was to develop those methods. The sales rep would come in and say "this guy wants to separate such and such, and

Page 273

get me a method so we can sell the instrument."
Q. Okay.
A. At that time liquid chromatography was nowhere near as advanced as it is now, so if a guy wanted to separate something, likely there was no published methods available many times, so then we would get involved.
Q. So were your years -- or your time at Waters dealing primarily with liquid chromatography?
A. Yes, or columns.
Q. Or columns.
Does that include your entire time at Waters up until February, 1980?
A. Yes. Developed amino acid, worked on developing an amino acid analyzer, first generation amino acid analyzer. And then they sent me places to install amino acid analyzers, like they sent me to Germany, they sent me to Chicago.
Q. Continuing in the analytical chemistry area?
A. Yeah, it was amino acid analysis at this point, that was the specialty at that point in time. It always kept changing depending on

Page 274

the needs of the company, of course.
Q. Then you went for a short time to LC Laboratories?
A. I'm looking at the order of these pages here.
Q. You go back to front, I think.
A. There's Army. The pages aren't listed.
MR. ANDERSON: Is this it here?
A. Where are we here?
BY MR. THOMAS:
Q. Hopefully February, 1980 to September, 1980, it looks like you were employed by LC Laboratories as a senior chemist?
A. That's right.
Q. You managed the complete polymer GPC program?
A. Right. I was working at the time with a Waters 150C, which is a high temperature GPC system running high temperature samples, among other things, and I was responsible for maintaining that instrument.
And we also were a contract lab, so we got all kinds of projects. Whatever the customers sent in they wanted us to do, we did,

Page 275

just like we have here now.
Q. Same kind of internal analytical work?
A. Yes.
Q. Okay.
A. It might be prep, it might be developing analytical method, it might be polymer formulation, whatever, whatever it was.
Q. And then from October of 1980 until July, 2008 you ran your own show?
A. That's right. Remember I told you four or five years, that's where it is. 2008 we turned it over to Mark.
Q. Has the business of Jordi Labs largely been the same over the time frame it's operated?
A. Yes. But we're continuing to add instrumentation. So some of the instruments we don't have now, if you come back in a few years, lord willing, we will have. Like we're thinking about an FTIR microscope system, we're thinking about an SEM system. We just invested in a QTOF GC system which should be in within the next few months to match the LCMS QTOF system, which gives you more accurate mass and better ability to get more accurate mass and more accurate identification of unknowns.

Page 276

Q. How would you describe the business of Jordi Labs today?
A. We're an analytical testing lab, material science, some expert witness testimony, it's not the major thrust by any stretch, product development. Because the other side of the business that I developed during my time is several dozen products, fluorinated gel that I patented that's selling.
Q. What does a fluorinated gel do?
A. Well, in chromatography, as you run fast -- liquid chromatography, or any chromatography, as you run faster you'll tend to get less efficient plates. Plates is a narrowness of the peaks coming off, and the narrower they are the better, the more things separated the narrower they are.
So with the fluorinated gel, solvents, it's like Teflon surface chemistry, solvents tend not to wet it. Since solvents don't wet surface, they don't create drag, and that's what broadens the peaks. And so now I can run something at 10 mils a minute instead of one mil a minute, I can run at one-tenth the time on that kind of column.

Page 277

I developed a polyamide type column, we call it Extreme. It's a column that runs things in water, polar solvents, so today our polyamides, nylons, proteins, can be run on the Extreme material.
I have a standard line of DVD resins that I've developed. Those are selling well.
And basically there's a whole product line. There's SFE product, solid face extraction cartridges.
Q. Is it fair to describe your business as a lab that offers analytical chemistry services to those who might need it?
A. Yes.
Q. And whatever other products you all might develop on your own?
A. The products we developed are no like -- I would say we probably have a million dollar column inventory here, if we had to go out and buy them all, but we save a good portion of that money by making them ourselves. And as a side bonus, we sell them on the side and make money from the sale of them, too, as products. That was my business model.
And when I successfully developed

Page 278

methods for clients, then they would say -- they might say "okay, now you run $100,000 worth or $200,000 worth of samples, I want to take that in-house, sell me the column, turn-key method." They've already seen my methods here, they've seen the results, they just take the column and start running. But now I don't use the total business, I have a column customer instead of a sample customer.

Q. So when you talk about the methods, you're talking about methods of analytical chemistry that you come up with for your customers?

A. Yes.

Q. Prior to your deposition today, have you ever testified or consulted in a medical device case?

A. I have testified. I don't think, I don't recall -- well, I have been involved with polypropylene implants, artificial hips, artificial knees, polyethylene, I believe. I've been involved with contact lenses. I don't -- I've been involved in the legal cases, many times they don't go to court, they settle, so you say testify, testifying has been less, of

Page 279

course, than the work for -- because people will come to me and not even tell me it's a legal case, then they'll see the results and then tell me they want to do more and now they'll tell me it's a legal case.

Q. What did you do in connection with knee implants?

A. I just ran GPC, additives.

Q. Analytical testing?

A. Just to see if the polymer was degraded over periods of time, if the additives were still there, just like we're doing now.

Q. Did you give any deposition testimony in any cases involving knee implants?

A. It's been 20 years ago. I don't recall. I remember running the work, but I don't remember what -- how deep into it we got.

Q. Did you work for the Plaintiff or the Defendant?

A. I worked for the manufacturer, whether --

Q. Do you remember who that was?

A. No, I don't.

Q. What about hip implants, what work did you do on hip implants?

Page 280

A. The same type of thing, molecular weight, additives.

Q. How long ago did you do the hip implant work?

A. The same thing.

Q. 20 years ago?

A. 20 years ago-ish.

Q. Have you done anything in the last ten years in hip implants?

A. No, I haven't seen it recently.

Q. Do you remember who you worked with on hip implants?

A. No.

Q. Did you give any depositions in hip implant litigation?

A. I don't think so.

Q. Do you know whether Jordi Labs works on any current hip implant litigation?

A. No. No, I shouldn't say -- I have to say I don't know because I really don't know what the current workflow is. I don't talk to the customers anymore directly. I used to know that intimately, but I don't now.

Q. Contact lenses, have you done any work on contact lenses in the last 15 years?

Page 281

A. I couldn't name the customers. I suspect we have because we've worked on methacrylate type gels, and hematype gels which are used in that kind of product.

Q. In a litigation context?

A. No, just analysis.

Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those cases?

A. No.

Q. Have you ever testified as an expert in a medical device case before today?

A. I don't believe so.

Q. Have you ever done any work for the FDA?

A. No.

Q. Ever done any work for Johnson & Johnson?

A. I think we probably have, because we've worked for almost all the major corporations over the years.

Q. Do you have a specific recollection of working for Johnson & Johnson or any of its subsidiaries?

Page 282

A. I have a recollection, but I couldn't even tell you what we did.
Q. Are you familiar with a company known as Ethicon?
A. Yes.
Q. Do you have any recollection of ever working with Ethicon?
A. The name sure sounds familiar.
Q. Do you know the business of Ethicon?
A. Well, I do, I mean I know one part of it at least now, these meshes. I don't know, I don't know what else they might be involved in.
Q. Do you know any business interests that Ethicon has beyond the mesh that's involved in the litigation about which you're testifying today?
A. Other than the mesh?
Q. Right.
A. No.
Q. And the only reason you know about the mesh and its relationship to Ethicon is because you're involved in this case, is that fair?
A. That's right.
Q. We talked earlier about work that Jordi Labs may be doing in litigation involving

Page 283

Bard. Do you know whether Jordi Labs is doing work involving the meshes of any other manufacturer?
A. I don't have any idea.
Q. Do you have an engagement letter with the Plaintiffs in this case?
A. No.
Q. Do you know whether Jordi Labs has an engagement letter with the Plaintiffs in the case?
A. Well, we have -- we send out quotations, and those have to be signed.
Q. Okay.
A. Somehow.
Q. For work that's been done in this case, you should have on your file a contract or agreement?
A. That would be -- the way the work is handled is it goes through a project manager, and the project manager would have that quote. He generates the quotes, and then it's approved by Mark and others.
Q. Do you know who the project manager is --
A. Greg.

Page 284

Q. -- for this work?
A. What's Greg's last name? I can look it up.
MR. ANDERSON: Elsdon.
A. Elsdon.
BY MR. THOMAS:
Q. And what kind of file materials would the company typically keep that would govern the relationship that it has with a customer, an engagement or purchase order or a contract of some sort outlining the work you're going to do?
A. There has to be some kind of paperwork, otherwise we wouldn't begin work.
Q. Anything else?
A. Not very formal, other than that.
Q. On the invoices we talked about earlier that I marked as an exhibit, there were a number of surcharges for rush work. Are you familiar with those?
A. Yes.
Q. What happened? Why were the surcharges made?
A. Well, like in the Batiste case, the sample was explanted recently, and we had to be ready for the deposition today, so in order to

Page 285

do that it had to be done on a rush basis or it wouldn't be ready. Normal turnaround is ten days.
Q. Do you have a pricing policy that determines the extent to which you markup work for surcharges?
A. Yeah, they do. It's maybe double. I don't -- again, I don't control that. But I'm familiar with it.
Q. For example, on invoice 7881, there's a surcharge for rush analytical surfaces of $35,000.
Would that be a charge in addition to what it ordinarily costs?
A. Yes.
Q. And again on 7883, 9/11/2013, there's another surcharge for $67,813?
A. Yes.
We're basically set up --
MR. ANDERSON: There's no question.
THE WITNESS: Sorry.
MR. ANDERSON: No question pending.
MR. THOMAS: I'm finished. Thank you.
MR. ANDERSON: All right. I need to take a break, take a few minutes and sit and

Page 286

talk, and we'll be back on here as soon as we can.

(Whereupon, a recess was taken from 5:16 p.m. to 5:49 p.m.)

CROSS EXAMINATION

BY MR. ANDERSON:

Q. Dr. Jordi, I'm just going to ask you a few questions. I know it's been a long day, but I just have a few follow-up questions to some of the things Mr. Thomas asked you. Okay?

A. Okay.

Q. Doctor, all of the testing that we've been discussing all day long that was performed by Jordi Labs, are all those tests industry standard?

A. Yes. Routine.

Q. In performing these tests, the ones that were done at Jordi Labs, were standard operating procedures here at Jordi Labs followed?

A. Yes.

Q. Were lab notebooks carefully collected and each step written down by --

A. Yes.

Q. Let me finish.

Page 287

-- by Jordi Labs?

A. Yes.

Q. And was all of the testing that we've described today done at your direction?

A. Yes, I requested these tests.

Q. Is it standard or non-standard in your industry for someone to assign work or to send work of this nature, this type of testing, to someone else to perform the testing?

A. It's standard procedure because nobody, almost nobody has enough, except the giants, has enough money to have all the instruments.

Q. So when Mr. Thomas was questioning you about some of the jobs you sent to Evans, and you said sometimes Evans sends jobs to you, is that standard in your industry?

A. Absolutely.

Q. Therefore, was it standard for you to send some of the FTIR microscopy and other tests out to Evans to have them send you the results?

A. Yes.

Q. In preparing your report in this case and providing your opinions, is it fair to say that you assigned these projects to folks at

Page 288

Jordi Labs, and they brought results back to you, and you interpreted those results?

A. That's right.

Q. Is that also standard in your industry?

A. Absolutely.

Q. In talking about your opinions regarding the degradation of the meshes from Ms. Batiste, Ms. Lewis, and the other women whose explant samples you reviewed today, do you have an opinion as to whether or not those meshes would degrade even if there were antioxidants present in the polypropylene?

MR. THOMAS: Object to the form of the question.

A. It's possible that they could if the amount of peroxide, superoxide, other oxidants, the irritation, the inflammation was great enough in a given patient.

BY MR. ANDERSON:

Q. You said "possible," so we have to correct that.

Do you have an opinion to a reasonable degree of medical certainty as to whether or not the meshes in Ms. Batiste, Ms. Lewis, and others

Page 289

could still degrade showing the cracking on SEM and showing SEM-EDX analysis of the particles to be polypropylene even if there was antioxidants present in the mesh?

MR. THOMAS: Object to the form of the question.

MR. ESTEE: Object to form.

A. It's certainly -- the antioxidants can be overcome if you throw enough oxidant at the polymer.

BY MR. ANDERSON:

Q. Is the sole basis for stating that antioxidants can leach from polypropylene just your work done in this case, or are there other bases for that opinion?

MR. THOMAS: Object to the form of the question.

A. Certainly additives bloom at varying rates depending on their compatibility with the polymer system they're put in. So Santonox R can bloom, most any additive can bloom at some rate, and the less compatible it is with the polymer the faster it will bloom, and hence the faster it will be lost. So polymers can lose their antioxidants even if they're stabilized

Page 290

initially. In fact, they all do at some rate.
BY MR. ANDERSON:
Q. And is that knowledge that you just expressed based only upon the studies that you did here, or is that something that you brought with you before this litigation?
MR. THOMAS: Object to the form of the question.
A. No, the -- over 30 years of experience and articles I've read, books I've read, other samples I've analyzed, it can be -- they can lose their antioxidants, as well as we showed it in the study. But that certainly isn't the only reason I believe they're lost.
BY MR. ANDERSON:
Q. Right at the end of some of the questioning there was some -- Mr. Thomas asked you some questions about some rush charges on the bills.
Do you remember those? Do you remember those questions?
A. Yes, sir.
Q. Is it standard in your industry if someone asks you to do a quick turnaround on testing that you charge a rush charge?

Page 291

A. Absolutely is.
Q. So that wasn't something just special to me, that's something your company does all the time?
A. We -- yes. Absolutely.
Q. Do other companies in your industry do the same thing?
A. Absolutely.
Q. Does your dry cleaners do it, too? Withdraw the question.
And why is it that your company would charge a rush fee?
A. We have to turn away other work, we have to put other projects on hold, potentially if we get enough of this type of thing, angering some clients. So it's a difficult management decision on how to handle it.
Q. Does it put an increase on your workload for your employees?
A. Absolutely.
Q. Let me take you back to a part of your testimony regarding cleaning the material or, let's call it, preparing the fibers prior to certain testing being done at Jordi Labs.
Do you remember that part of your

Page 292

questioning?
A. Mm-hmm.
Q. Yes?
A. Yes.
Q. There was some question by Mr. Thomas as to whether or not you should have used sodium hypochlorite in order to clean the materials.
Do you remember that part of the questioning?
A. Yes.
MR. THOMAS: Object to the form of the question.
MR. ANDERSON: I'm trying to redirect the witness back to that area of the questioning.
BY MR. ANDERSON:
Q. By not applying sodium hypochlorite to the fibers in order to remove some of the proteins, would that change any of your opinions with regard to whether or not the meshes in Ms. Lewis, Ms. Batiste, and the other women whose explanted meshes you looked at degraded on SEM analysis?
A. No. The fact is that you could clearly see the degradation, it had no bearing

Page 293

whatsoever.
Q. What change, if any, would applying sodium hypochlorite have to any of the test results that you obtained for Ms. Lewis, Ms. Batiste, and the other women?
A. It would have removed the protein from the surface of the mesh so that the infrared spectrum would -- the protein bands in the infrared spectrum would have gone away.
Q. Whether or not those bands are present or not present, can you still see other evidence of oxidation on those bands?
A. We still saw the 1760 band and the 1740 shoulder in spite of that. So they're both still there, both of which indicate oxidation.
Q. You were shown by Mr. Thomas Jordi Exhibit 3, that was this Renaud de Tayrac and Letouzey article.
Do you recall that?
A. Yes, I do.
Q. Were the meshes that were --
A. I got it.
Q. Were the meshes that were explanted and analyzed in that study coming from women?
A. No, it says in Figure 1 they were

Page 294

coming from Wistar rats.
Q. From rats, is that what you said?
A. Yes. Wistar rats.
Q. And when animal studies are used in a preclinical model, do they typically use healthy rats?
A. Yes.
Q. Was the explanted tissue coming from these women coming from healthy tissue?
MR. THOMAS: Object to the form of the question.
A. From here, from this figure?
BY MR. ANDERSON:
Q. From the women whose explanted meshes you looked at. I'll withdraw -- that's okay, I'll withdraw the question.
He used D -- well, these authors used DMSO as well as ultrasonic treatment in order to remove what they claim to be just the proteins from the fibers.
Do you recall that?
A. I do.
Q. Do you believe that's a scientifically valid method in which to determine what is flaking off of the meshes?

Page 295

A. I do not.
Q. And why is that?
A. If you use sonication you're using a battering ram to knock the cracked material off, and so if you knock the material off you're removing the very thing that you want to look at. They did not -- now, if they had run infrared or some other technique to look at the structure of the material coming off chemically, it would have been helpful, but none of that was done. So it was just blasted clean, and say it never was polypropylene, but we know it was polypropylene because we looked at it in our particles, and we saw that it was polypropylene. Of course it did have some protein in it, but it was mostly polypropylene.
Q. So do you find this article to be scientifically reliable with regard to whether or not TVT mesh degrades in women? Do you find this article to be scientifically valid with regard to whether or not the TVT meshes degrade in women?
A. I do not. I think -- I'm surprised it was published without some requirement to do structural analysis to prove their claim.

Page 296

There's no proof there by any chemical testing.
Q. Do you recall during part of your -- during part of the questioning by Mr. Thomas, he was asking you whether or not you or someone at Jordi Labs performed any analysis on hydrogen peroxide or any other products of inflammation that may have occurred in the women's tissue before these meshes were explanted? Do you remember that part of your testimony?
A. I do.
Q. Are you aware of any test out there that would allow you to look at the products of inflammation in and around mesh fibers that have been explanted and put into formalin and shipped to you for analysis?
A. Absolutely not, because it's been washed away.
Q. Would it matter to your opinions regarding the degradation of these meshes in this case whether or not hydrogen peroxide was present in the body at that time?
A. No, it would not, because the damage was observed in SEM and other techniques, like IR.
Q. Do you, to a reasonable degree of

Page 297

medical -- to a reasonable degree of medical certainty --
MR. THOMAS: Scientific certainty.
BY MR. ANDERSON:
Q. What did I say? Medical? It's been a long day.
Doctor, do you have an opinion to a reasonable degree of scientific certainty as to whether or not you need to know whether hydrogen peroxide, superoxides, or any other mediators or inflammatory products that would have been produced in the body were present on the meshes by the time you analyzed them in order to determine whether or not these meshes degraded?
A. I don't see why we'd need to determine that.
Q. And why is that?
A. It wouldn't matter. We see the degradation, the oxidation has already occurred, we don't need to say hydrogen peroxide or hydroxide radicals at this point, we need to see the chemical damage that's been done to the material. It either has or has not occurred.
Q. Do you recall some questioning by Mr. Thomas where you were looking at the FTIR

Page 298

microscopy, and there was a picture of one of the shards of polypropylene that had come off one of the meshes?
A. Yes.
Q. Do you recall that? Don't cut me off if you can.
Do you recall that?
A. Yes.
Q. Do you recall that he asked you how many of these particles came off of the fibers? Do you remember that?
A. Yes.
Q. Did you feel the need to count each and every particle that came off of those fibers in order to allow you to make an opinion as to whether or not those FTIR microscopy analyses showed that the shards contained polypropylene?
A. I saw no need, because you can look at the cracked region, and if it came off in bits and pieces, each piece would be the same. It all looks identical.
Q. And just give us an estimate of how many of these particles were falling off just one of these small pieces of fibers; are we talking tens, twenties, dozens?

Page 299

A. I have no idea.
Q. It's that many?
MR. THOMAS: Object to form.
A. In some cases, like this case, this article --
BY MR. ANDERSON:
Q. No, we're going to focus on in this case.
A. Okay.
Q. The amount of material. Let's focus on that.
In the photographs that were done by Evans on the FTIR microscopy when they showed the various pieces, did you need to test 10, 20, 30 of those pieces to confirm the results that you had on your FTIR microscopy?
MR. THOMAS: Object to the form of the question.
A. No. I mean they're all the same.
BY MR. ANDERSON:
Q. Do you recall being asked a question as to how much oxidation is required to cause the polypropylene fibers to begin to flake? Do you recall that part of your questioning?
A. Yes.

Page 300

Q. How much oxidation was required for Ms. Lewis, Ms. Batiste, and these other 21 women?
A. Enough to cause the flaking that was observed.
MR. THOMAS: Object to form of the question. Move to strike.
MR. ESTEE: Object to form.
BY MR. ANDERSON:
Q. How much oxidation was required for the mesh samples for Linda Batiste, Carolyn Lewis, and all the other women whose meshes you observed in order to flake?
MR. THOMAS: Object to the form of the question.
MR. ESTEE: Form.
A. That's an impossible question for me to answer. I know that there was enough because it did flake and it was observed in the SEM.
BY MR. ANDERSON:
Q. If polypropylene fibers flake in the manner in which those that you observed in this testing flaked and peeled off, would that allow this mesh to function for its intended purpose?
MR. THOMAS: Object to form of the

Page 301

question.
MR. ESTEE: Object to form.
A. I would think it would cause irritation in the body, so I would think not. That is a question primarily for the medical doctors to answer as far as the damage it might or might not do. But it certainly can't be good to be putting knife edges in tissue.
BY MR. ANDERSON:
Q. Is it your understanding that these are supposed to be permanently implanted in a woman's pelvic tissues?
A. Yes.
Q. Given the amount of degradation that you've seen in your testing, do you believe that it would perform its intended purpose of being permanently implanted in these women's bodies without causing some problems with the polymer structures?
MR. THOMAS: Object to the form of the question.
A. Absolutely not.
BY MR. ANDERSON:
Q. Explain what you mean by that.
A. Well, these shards come off, they're

Page 302

going to cause inflammation, and it's going to be a problem.
MR. THOMAS: Move to strike.
BY MR. ANDERSON:
Q. Had these meshes continued to be in these women's bodies, would you -- strike that.
Is degradation of polymer, like you've seen in this testing, progressive?
MR. THOMAS: Object to form of the question.
A. Yes. It definitely is. It starts on the surface and apparently works its way in, as we've seen by SEM-EDX presence of oxygen in the second underlying layer.
BY MR. ANDERSON:
Q. So do you have an opinion to a reasonable degree of scientific certainty as to whether or not the longer these mesh fibers are in the body the more degradation will occur? Do you have an opinion on that?
A. I think the data shows that it's going to degrade like the layers of an onion, layer after layer.
Q. You were asked some questions about -- from Mr. Thomas as to whether or not you used a

Page 303

standard over here for polypropylene, for FTIR, or a standard over here. Do you remember that part of your questioning?
A. Right.
Q. Do you need an FTIR for polypropylene -- sorry. Strike that.
Do you need an FTIR standard for polypropylene in order to determine whether or not the polypropylene in these meshes oxidized and degraded?
A. Absolutely not.
Q. Please explain that.
A. Because we have -- the carbonyl is going to show up at 1740, 1730, 17 whatever, 15, or 1700 depending on the form, or a mix of all of those, and that's going to be there in a polypropylene. So if the carbonyl shows up, it's going to be separate from the bands of the polypropylene. Polypropylene doesn't have any bands there.
Q. Do you recall, if you could just turn to Pages 67 and 69 of your report, you were looking at some FTIR micro with Mr. Thomas?
A. Yes.
Q. And you were asked some questions as

Page 304

to whether or not you found anything in the FTIR, evidence of oxidation at band 1730 to 1680.
Do you recall that?
A. Yes.
Q. Does it matter to you whether or not you can find evidence of oxidation in the FTIR at 1730 to 1680 in order to hold the opinion that this mesh degraded in this woman's body?
A. Not really, because the fact is it did degrade and we saw it in the SEM. That's just simply a fact.
Q. Is all of the testing that was done for Carolyn Lewis and Linda Batiste contained in the reports that you've provided?
A. Was all of the testing?
Q. Is all of the testing that was done at your direction provided in the reports that you've given today for both Linda Batiste and Carolyn Lewis?
A. Well, with the possible exception of the --
Q. Let me see if I can withdraw that.
Is all the testing that forms the basis of your opinions that the mesh degraded in

Page 305

Linda Batiste and Carolyn Lewis available in the reports that you've provided today?
A. Yes.
MR. THOMAS: Object to the form of the question.
BY MR. ANDERSON:
Q. In other words, if you wanted to speak to the results for all of the testing that was done showing degradation as you've described previously here for the jury for Carolyn Lewis and Linda Batiste, you'd be able to point us to each one of those testing as Mr. Thomas went through with you today, correct?
MR. THOMAS: Object to form.
MR. ESTEE: Form.
MR. ANDERSON: Form.
A. That's correct.
BY MR. ANDERSON:
Q. Based on your knowledge, training, background, experience, your work history with polymers as you described it here today, your work as a biochemist and a polymer chemist, and all of the materials that you reviewed in this case, including the testing that was done at your direction, do you have an opinion to a

Page 306

reasonable degree of scientific certainty as to whether or not the polypropylene mesh, Prolene mesh TVT implanted in Carolyn Lewis, degraded while in her body?
MR. THOMAS: Object to the form of the question.
MR. ESTEE: Object to form.
BY MR. ANDERSON:
Q. Do you have an opinion?
A. I absolutely do.
Q. What is that opinion?
MR. THOMAS: Objection to form.
MR. ESTEE: Form.
A. It's obvious, you can see the cracking.
BY MR. ANDERSON:
Q. And do you have an opinion to a reasonable degree of scientific certainty based upon your knowledge, training, background, education, all of your work history for greater than 30 years, 40 years, your work here at Jordi Labs, as well as all of the materials that you've reviewed in this case, including the testing that was done for the explant sample for Linda Batiste, as to whether or not the mesh in

Page 307

Linda Batiste degraded in her body?
MR. THOMAS: Objection.
MR. ESTEE: Form.
A. It did degrade. I saw the damage.
BY MR. ANDERSON:
Q. And what is the basis for that, the damage that you saw, the testing that you saw?
MR. THOMAS: Objection.
A. We saw increased carbonyls in the infrared. We saw the increased oxygen in SEM-EDX. We saw the lack of antioxidants, which would predispose the polymer to oxidation.
BY MR. ANDERSON:
Q. Did the SEM photos also support your opinions in that regard?
A. They were the -- they were proof positive really. That just shows it's fact, it happened. We can argue about how it happened, but it's definitely a fact that it did happen.
MR. ANDERSON: I don't have anything further.
MR. THOMAS: Anybody on the phone?
MR. ESTEE: I'm sorry?
MR. THOMAS: Do you have any questions?

Page 308

MR. ESTEE: No. We will reserve any questions until the time of trial.
MR. THOMAS: Thank you.
(Whereupon, the deposition was concluded at 6:11 p.m.)

Page 309

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)
I, MAUREEN O'CONNOR POLLARD, RPR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 30th day of October, 2013, at 9:05 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.
In witness whereof, I have hereunto set my hand this 1st day of November, 2013.

_____
MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A

PAGE LINE CHANGE

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

HOWARD C. JORDI, PH.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

PAGE LINE

____ ____ _____